

they are consistent with this reorganization.

Dated: September 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-24583 Filed 9-23-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail paperwork@hrsa.gov or call the HRSA

Reports Clearance Officer at (301) 443-1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (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: Cultural and Linguistic Competency and Health Literacy Data Collection Checklist (OMB No. 0915-xxxx)—[New]

The vision of the Health Resources and Services Administration (HRSA) is "Healthy Communities, Healthy People." In addition, the HRSA mission statement is "To improve health and achieve health equity through access to quality services, a skilled health workforce and innovative programs." This is the framework that supports a health care system that assures access to comprehensive, culturally competent, quality care.

Performance measures have been helpful for HRSA to assess the progress of each grantee. The measure used will be the degree to which HRSA-funded

programs have incorporated cultural and linguistic competence and health literacy elements into their policies, guidelines, contracts and training. HRSA Bureaus/Offices shall be encouraged to incorporate this performance measure or a modified version of this measure into their funding opportunity announcements either as a stand-alone or integrated measure.

Using a scale of 0-3, the grantee may use the Cultural and Linguistic Competency and Health Literacy Data Collection Checklist to assess if specified cultural/linguistic competence and health literacy elements have been incorporated into their policies, guidelines, contracts and training. Each HRSA program may add data sources and year of data used for scoring to provide a rationale for determining a score, and/or applicability of elements to a specific program.

The goal of this checklist is to increase the number of HRSA-funded programs that have integrated both cultural and linguistic competence, as well as health literacy, into their policies, guidelines, contracts and training. In addition, variations of the proposed tool have proven useful for grantees' self-assessment. This proposed tool can also offer insights into technical assistance challenges and opportunities.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Data Collection Checklist	900	1	900	1	900
Total	900	1	900	1	900

E-mail comments to paperwork@hrsa.gov or mail the HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: September 20, 2011.

Reva Harris,

Acting Director, Division of Policy Information and Coordination.

[FR Doc. 2011-24561 Filed 9-23-11; 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.

A Novel Method To Predict Kidney Tumor Growth

Description of Technology: The invention pertains to a computerized method of predicting kidney tumor growth for early stage treatment planning. The method utilizes a finite

element method (FEM)-based 3D tumor growth prediction system using longitudinal kidney tumor images. The kidney tissues are classified into three types: Renal cortex, renal medulla and renal pelvis. The reaction-diffusion model is applied as the tumor growth model. Different diffusion properties are considered in the model: Anisotropic for renal medulla and isotropic for renal cortex and renal pelvis. The FEM is employed to solve the diffusion model. The model parameters are estimated by optimizing of an objective function. Ultimately, longitudinal data is used to fit the tumor growth model. The technique was tested on two longitudinal studies with seven time points on five tumors. The experimental results (average of 91.4% true positive volume fraction and 4.0% of false positive volume fraction) showed the feasibility and efficacy of the technique.

Potential Commercial Applications: The technique can be used to predict kidney tumor growth pattern using CT data. It can be effectively used in planning therapeutic regimen in early stage kidney tumors.

Competitive Advantages: The technique is the first kidney tumor growth prediction system. It can be implemented in the oncology package that most major imaging companies have in their commercial workstation.

Development Stage:

- Prototype.
- In vivo data available (human).

Inventors: Ronald M. Summers et al. (NIHCC).

Publication: Chen X, et al. FEM-Based 3-D Tumor Growth Prediction for Kidney Tumor. *IEEE Trans Biomed Eng.* 2011 March;58(3):463-467; doi 10.1109/TBME.2010.2089522.

Intellectual Property: HHS Reference E-250-2011/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Michael Shmilovich, Esq.; 301-435-5019; shmilovm@mail.nih.gov.

Pharmaceutical Compounds for the Treatment of Spinal Muscular Atrophy and Other Uses

Description of Technology: The SMA Project (<http://www.smaproject.org/programs.html>) was established by NINDS to identify new compounds with improved effectiveness, safety, and pharmacokinetic characteristics aimed at finding a new therapeutic treatment for Spinal Muscular Atrophy (SMA), a paralyzing and often fatal disease of infants and children. The result of the SMA Project medicinal chemistry optimization effort is a library of ~1400 indoprofen analogues with drug like

properties. A lead pre-clinical candidate for SMA has been identified based on several factors, including its ability to increase SMN expression.

The mechanism by which these compounds affect ribosomal fidelity proves to be useful for many genetic CNS diseases. The ability of these compounds to read through nonsense stop codons, coupled with the ability to cross the blood-brain barrier and drug like properties, makes these compounds attractive as therapeutics for diseases such as Muscular Dystrophy and Cystic Fibrosis. Preliminary results in HIV and HPV assays show that these compounds potentially inhibit viral replication, presumably via inducing ribosomal frame shift, suggesting potential for antiviral therapy. In addition, these compounds have been shown to be non-toxic and well-tolerated at high doses in rodents.

Potential Commercial Applications: Broad applications based on mechanism of action—

- Read through = many genetic CNS diseases.

—Spinal Muscular Atrophy (SMA) .

—Muscular Dystrophy, Rett Syndrome, Diabetes Cancer, Niemann Pick disease, Cystic Fibrosis.

- Frame shift = broad anti-viral.

—Efficacy similar to AZT in HIV replication assay.

—Effective suppression of HPV replication.

—Brain penetrant compounds → neuronal viruses.

Competitive Advantages:

- No treatments available for SMA.
- First-in-class anti-viral with host-directed mechanism of action.

• Optimized activity and pharmaceutical properties:

—nM potency and efficacy in SMN expression assays.

—Good brain penetrance.

—Metabolic stability in multiple species.

—Demonstrated favorable ADMET characteristics.

—Demonstrated safety in 7-day rat tox studies.

—High yield synthesis process.

Development Stage:

- Early-stage.
- Pre-clinical.
- In vitro data available.
- In vivo data available (animal).

Inventors: Jill E. Heemskerk (NINDS), et al.

Intellectual Property: HHS Reference No. E-050-2011/0—U.S. Patent Application No. 61/475,541 filed 14 April 2011.

Related Technologies:

- HHS Reference No. E-133-2006/1—U.S. Patent Application No. 12/293,268 and foreign patent applications.

- HHS Reference No. E-187-2007/0—U.S. Patent Application No. 12/680,285 and foreign patent applications.

Licensing Contact: Charlene A.

Sydnor, Ph.D.; 301-435-4689;

sydnorc@mail.nih.gov.

Collaborative Research Opportunity: The National Institute of Neurological Disorders and Stroke is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize treatment for SMA. For collaboration opportunities, please contact Melissa Maderia at maderiam@mail.nih.gov.

STAMP, A Novel Cofactor and Possible Steroid Sparing Agent, Modulates Steroid-induced Induction or Repression of Steroid Receptors

Description of Technology: Steroid hormones such as androgens, glucocorticoids, and estrogens are used in the treatments of many diseases. They act to regulate many physiological responses by binding to steroid receptors. However, because steroid receptors are expressed in many tissues, efforts to therapeutically modify the effects of steroid hormones on a specific tissue or on a specific receptor of the steroid receptor family often cause undesirable effects in other tissues or on other receptors. STAMP (SRC-1 and TIF-2 Associated Modulatory Protein), a novel protein that acts to lower the concentration of steroid hormone needed to induce (or repress) selected target genes by regulating steroid receptor synthesis, offers a novel approach for reducing the severity of unwanted side-effects, thereby increasing the ability to use steroid hormone therapies.

Potential Commercial Applications:

- Diseases requiring chronic steroid treatment such as rheumatoid arthritis, psoriatic arthritis, asthma, inflammatory and auto-immune diseases.

- Diseases characterized by excess or deficiency of glucocorticoids such as obesity, diabetes, hypertension, Cushing's Syndrome, Parkinson's Disease, Addison's Disease.

- Diseases in which glucocorticoid-responsive gene expression is deranged, so deranging carbohydrate, protein or lipid metabolism.

- Cancers responsive to androgen or estrogen, such as breast cancer or prostate cancer.

- Therapeutic applications related to male or female hormone replacement, symptoms related to menopause, birth control, menstrual cycle/amenorrhea, fertility or endometriosis.

Competitive Advantages:

- STAMP reduces the severity of unwanted side-effects of steroid hormone therapies.

- STAMP modulates the gene induction properties of androgen and progesterone receptors.

- STAMP modulates both induction and repression properties of glucocorticoid receptors.

- STAMP is inactive toward alpha and beta estrogen receptors, thyroid receptor beta, PPAR gamma 2, retinoid receptor alpha or RXR alpha.

- The siRNAs could be useful as therapeutics.

Development Stage: Early-stage.

Inventors: S. Stoney Simons Jr. and Yuanzheng He (NIDDK)

Publication: He Y, Simons SS Jr. STAMP, a novel predicted factor assisting TIF2 actions in glucocorticoid receptor-mediated induction and repression. *Mol Cell Biol.* 2007 Feb;27(4):1467–1485. [PMID 17116691].

Intellectual Property: HHS Reference No. E-056–2004/0—U.S. Patent No. 7,867,500 issued 11 Jan 2011.

Related Technology: HHS Reference No. E-226–2009/0—PCT Application No. PCT/US10/037452 filed 04 Jun 2010, which published as WO 2010/144324 on 16 Dec 2010.

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

Collaborative Research Opportunity: The National Institute of Diabetes and Digestive and Kidney Diseases, 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 Dr. S. Stoney Simons at steroids@helix.nih.gov for more information.

A Biomarker and Therapeutic Target for Ovarian Cancer

Description of Technology: This technology provides methods of diagnosing or treating certain ovarian cancers using STAMP, a steroid cofactor. 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 have 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 a siRNA-based therapy for ovarian cancer.

Development Stage:

- Early-stage.

- In vitro data available.

Inventors: S. Stoney Simons and Yuanzheng He (NIDDK).

Publication: He Y, et al. STAMP alters the growth of transformed and ovarian cancer cells. *BMC Cancer.* 2010 Apr 7;10:128. [PMID 20374646].

Intellectual Property: HHS Reference No. E-226–2009/0—PCT Application No. PCT/US10/037452 filed 04 Jun 2010, which published as WO 2010/144324 on 16 Dec 2010.

Related Technology: HHS Reference No. E-056–2004/0—U.S. Patent No. 7,867,500 issued 11 Jan 2011.

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

Collaborative Research Opportunity: The National Institute of Diabetes and Digestive and Kidney Diseases, 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 Dr. S. Stoney Simons at steroids@helix.nih.gov for more information.

Small Molecule Modulators of Adrenomedullin and Gastrin Releasing Peptide for the Treatment of Cancer and Other Angiogenesis-Mediated Disorders

Description of Technology:

Adrenomedullin (AM) and Gastrin Releasing Peptide (GRP) are peptide hormones that are expressed in a wide range of tissues and have a variety of biological roles, including angiogenesis, cardiovascular disease, renal function, cell growth, glucose metabolism, and regulation of hormone secretion.

The inventors have identified a panel of small molecule, non-peptide, pharmaceutically active compounds that modulate AM or GRP activity at nanomolar concentrations. Certain antagonists in the panel were demonstrated to inhibit angiogenesis and inhibit cell proliferation *in vitro*, and to reduce tumor size in an *in vivo* rodent model. These modulatory compounds may be useful in the

treatment of a number of diseases related to aberrant angiogenesis, particularly cancer.

This technology describes methods of inhibiting aberrant activity of AM or GRP using a compound identified by the inventors, as well as methods of treating a condition by such inhibition, such as cancer, hypotension, and other disorders. Also described are pharmaceutical compositions, kits, and methods for detecting an AM or GRP peptide using the compounds.

Potential Commercial Applications:

Treatment of angiogenesis-mediated diseases such as cancer, cardiovascular disease, and macular degeneration.

Competitive Advantages:

- Compounds effective at nanomolar concentrations.

- Extensive *in vitro* and *in vivo* data available for several compounds.

Development Stage:

- Early-stage.

- *In vitro* data available.

- *In vivo* data available (animal).

Inventors: Frank F. Cuttitta and Alfredo Martinez (NCI).

Publications:

1. Martinez A, et al. Identification of vasoactive nonpeptidic positive and negative modulators of adrenomedullin using a neutralizing antibody-based screening strategy. *Endocrinology.* 2004 Aug;145(8):3858–3865. [PMID 15107357].

2. Martinez A, et al. Gastrin-releasing peptide (GRP) induces angiogenesis and the specific GRP blocker 77427 inhibits tumor growth *in vitro* and *in vivo*. *Oncogene.* 2005 Jun 9;24(25):4106–4113. [PMID 15750618].

3. Martínez-Murillo R, et al. Standardization of an orthotopic mouse brain tumor model following transplantation of CT-2A astrocytoma cells. *Histol Histopathol.* 2007 Dec;22(12):1309–1326. [PMID 17701911].

4. Fang C, et al. Non-peptide small molecule regulators of lymphangiogenesis. *Lymphat Res Biol.* 2009 Dec;7(4):189–196. [PMID 20143917].

Intellectual Property:

- HHS Reference No. E-246–2003/1—U.S. Application No. 10/571,012 filed 08 Mar 2006.

- Foreign counterparts in Australia, Canada, and Europe.

Related Technologies:

- HHS Reference No. E-206–1995/3.

- HHS Reference No. E-256–1999/0.

- HHS Reference No. E-293–2002/0.

- HHS Reference No. E-294–2002/0.

- HHS Reference No. E-263–2009/0.

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

Dated: September 20, 2011.

Richard U. Rodriguez,

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

[FR Doc. 2011-24626 Filed 9-23-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group, Subcommittee J—Population and Patient-Oriented Training.

Date: October 27, 2011.

Time: 7:45 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Westin Alexandria, 400 Courthouse Square, Alexandria, VA 22314.

Contact Person: Ilda M. McKenna, PhD, Scientific Review Officer, Research Training Review Branch, Division Of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8111, Bethesda, MD 20892, 301-496-7481, mckennai@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: <http://deainfo.nci.nih.gov/advisory/irg/irg.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 19, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-24646 Filed 9-23-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Hypertension and Microcirculation A.

Date: October 14, 2011.

Time: 11 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Anshumali Chaudhari, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4124, MSC 7802, Bethesda, MD 20892, (301) 435-1210, chaudhaa@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Gastrointestinal Pathophysiology.

Date: October 20, 2011.

Time: 12 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Patricia Greenwel, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, MSC 7818, Bethesda, MD 20892, 301-435-1169, greenwep@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 20, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-24648 Filed 9-23-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Nursing Research Special Emphasis Panel, Institutional Research Training Grant.

Date: October 19, 2011.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Weiqun Li, MD, Scientific Review Administrator, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Blvd., Ste. 710, Bethesda, MD 20892, (301) 594-5966, wli@mail.nih.gov.

Name of Committee: National Institute of Nursing Research Special Emphasis Panel, Fellowship and Career Award Grant Review with Conflict.

Date: October 21, 2011.

Time: 8 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Weiqun Li, MD, Scientific Review Administrator, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Blvd., Ste. 710, Bethesda, MD 20892, (301) 594-5966, wli@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)