The annual estimate of burden is as follows:

Form name	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Medicare Rural Hospital Flexibility Grant Program	45	1	45	216	9,720
Total	45	1	45	216	9,720

ADDRESSES: Submit your comments to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

Deadline: Comments on this ICR should be received within 30 days of this notice.

Dated: April 22, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–09946 Filed 4–25–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Health Center Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Noncompetitive Replacement Award to Genesee Health System.

SUMMARY: The Health Resources and Services Administration (HRSA) will be transferring Health Center Program (section 330 of the Public Health Service Act) funds originally awarded to the County of Genesee to ensure the provision of critical primary health care services to underserved populations in Genesee County, Michigan.

SUPPLEMENTARY INFORMATION:

Former Grantee of Record: County of Genesee.

Original Period of Grant Support: June 1, 2012, to April 30, 2014.

Replacement Awardee: Genesee Health System.

Amount of Replacement Award: The original award to the County of Genesee was issued as a result of a New Access Point application. The County of Genesee and Genesee Health System have agreed that the funds to be transferred will be the remaining amount in the account as of the date of this transfer.

Period of Replacement Award: The period of support for the replacement award is May 1, 2013, to April 30, 2014.

Authority: Sections 330 of the Public Health Service Act, 42 U.S.C. 245b.

CFDA Number: 93.224.

Justification for the Exception to Competition: The former grantee, the County of Genesee, has requested that HRSA transfer a Health Center Program section 330 grant to Genesee Health System to implement and carry out grant activities originally proposed under the County of Genesee's funded section 330 grant application. Genesee County Community Mental Health (GCCMH)—now Genesee Health System—was formerly a department of the County of Genesee and has continued to carry out the operations of the grant program since its award in June 2012. On January 1, 2013, the State of Michigan approved GCCMH's independence as a separate public governmental entity, and GCCMH was legally renamed the Genesee Health System. The Genesee Health System is directly engaged in the delivery of primary health care services on the County of Genesee's behalf and has indicated an ability to continue operations without a disruption of services.

Genesee Health System is currently providing primary health care services on behalf of the County of Genesee to the original target population and is located in the same geographical area. This underserved target population has an immediate need for vital primary health care services and would be negatively impacted by any delay or disruption of services caused by a competition. As a result, in order to ensure that critical primary health care services remain available to the original target population without disruption, this replacement award will not be competed.

FOR FURTHER INFORMATION CONTACT: Kirsten Argueta, Senior Advisor, North Central Division, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, MD 20857, via email at *KArgueta@hrsa.gov* or (301) 594–1055.

Dated: April 19, 2013.

Mary K. Wakefield,

Administrator.

[FR Doc. 2013–09942 Filed 4–25–13; 8:45 am]

BILLING CODE 4165–15–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.

FOR FURTHER INFORMATION CONTACT: 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.

Zirconium-89 PET Imaging Agent for Cancer

Description of Technology: This technology is a new generation of rationally designed chelating agents which improve the complexation of Zirconium-89 for PET imaging of cancers. The technology uses cyclic or acyclic chelators made of 4 hydroxamate donors groups for improved stability compared to the currently used natural product siderophore desferrioxamine B (DFB), a

chelator that consists of only 3 hydroxamate donors that fails to saturate the coordination sphere of Zr(IV). DFB, which has been the object of many pre-clinical and clinical studies exhibits insufficient stability resulting in progressive radioisotope accumulation in bone once injected that can contribute to toxicity and increased background. The new chelators described in this invention have shown improved kinetic inertness compared to DFB with stability up to 90% after 7 days compared to 28% for DFB. In association with an adequate targeting agent such as an antibody, toxicity to the bone can be reduced and images with better contrast can be obtained with these new chelators.

Potential Commercial Applications:

- Cancer imaging.
- PET imaging.
- ImmunoPET.

Competitive Advantages:

- High stability.
- Low toxicity.
- Better imaging contrast.

Development Status:

- Prototype.
- *In vitro* data available.

Inventors: Francois Guerard (NCI), Yong Sok Lee (CIT), Martin Brechbiel (NCI).

Publications:

1. Zhou Y, et al. Mapping biological behaviors by application of longer-lived positron emitting radionuclides. Adv Drug Deliv Rev. In Press; doi: 10.1016/j.addr.2012.10.012. [PMID 23123291].

2. Deri MA, et al. PET imaging with 89Zr: from radiochemistry to the clinic. Nucl Med Biol. 2013 Jan;40(1):3–14. [PMID 22998840].

3. Vosjan MJ, et al. Conjugation and radiolabeling of monoclonal antibodies with zirconium-89 for PET imaging using the bifunctional chelate p-isothiocyanatobenzyl-desferrioxamine. Nat Protoc. 2010 Apr;5(4):739–43. [PMID 20360768].

4. Nayak TK, et al. PET and MRI of metastatic peritoneal and pulmonary colorectal cancer in mice with human epidermal growth factor receptor 1-targeted 89Zr-labeled panitumumab. J Nucl Med. 2012 Jan;53(1):113–20. [PMID 22213822].

5. Evans MJ, et al. Imaging tumor burden in the brain with 89Zr-transferrin. J Nucl Med. 2013 Jan;54(1):90–5. [PMID 23236019].

6. Guerard F, et al. Investigation of Zr(IV) and 89Zr(IV) complexation with hydroxamates: progress towards designing a better chelator than desferrioxamine B for immuno-PET imaging. Chem Commun (Camb). 2013 Feb 1;49(10):1002–4. [PMID 23250287].

Intellectual Property: HHS Reference No. E–111–2013/0—U.S. Provisional Application No. 61/779,016 filed 13 Mar 2013.

Related Technologies:

- HHS Reference No. E–194–2007/0—U.S. Patent Application No. 12/667,790 filed 05 Jan 2010.
- HHS Reference No. E–226–2006/0—U.S. Patent No. 8,288,530 issued 16 Oct 2012.
- HHS Reference No. E–067–1990/0.

Licensing Contact: Michael A. Shmilovich; 301–435–5019; *shmilovm@mail.nih.gov*.

Collaborative Research Opportunity: The Radioimmune & Inorganic Chemistry Section, ROB, CCR, NCI, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Zirconium-89 chelation technology for ImmunoPET imaging and other applications. For collaboration opportunities, please contact John D. Hewes, Ph.D. at *hewesj@mail.nih.gov*.

Novel Methods for Generating Retinal Pigment Epithelium Cells From Induced Pluripotent Stem Cells

Description of Technology: High efficiency methods for producing retinal pigment epithelial cells (RPE) from induced pluripotent stem cells (iPSCs) are disclosed. The RPE is a polarized monolayer in the vertebrate eye that separates the neural retina from the choroid, and performs a crucial role in retinal physiology by forming a blood-retinal barrier and closely interacting with photoreceptors to maintain visual function. Many ophthalmic diseases, such as age-related macular degeneration, are associated with a degeneration or deterioration of the RPE. The iPSCs are produced from somatic cells, including retinal pigment epithelial cells, such as fetal RPE. These methods involve producing embryoid bodies from human iPSCs, culturing the embryoid bodies using specific media to induce differentiation into RPE and growing the differentiated RPE cells in a defined media to generate human RPE cells. The investigators also developed methods for detecting RPE cells and authenticating RPE cells; determining agents that can affect the production of RPE cells from an iPSC; and identifying an agent that can increase RPE survival in response to a proteo toxic insult or stress. The novel methods and RPE cells disclosed here can be useful for both pre-clinical and clinical studies involving RPE.

Potential Commercial Applications: The methods described here can be used to:

- Produce RPE cells for use in screening for novel ocular therapeutics and for identifying toxic side effects of drugs.
- Produce RPE cells for use in novel cell-based therapies.
- Produce cells to study pathophysiology of RPE.

Competitive Advantages: The methods described here:

- Dramatically increase the efficiency of iPSC differentiation into RPE.
- Produce superior quality RPE.
- Produce RPE cells that are fully authenticated.
- Provide ways to perform high throughput screens with RPE cells.

Development Stage:

- Prototype.
- Early-stage.
- In vitro data available.

Intellectual Property: HHS Reference No. E–251–2012/3—U.S. Provisional Application No. 61/759,988 filed 01 Feb 2013.

Licensing Contact: Suryanarayana (Sury) Vepa; 301–435–5020; *vepas@mail.nih.gov*.

Collaborative Research Opportunity: The National Eye Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize iPSC to RPE differentiation protocol, its clinical, screening, and translational applications. For collaboration opportunities, please contact Alan Hubbs, Ph.D. at *hubbsa@mail.nih.gov*.

Novel Tocopherol and Tocopheryl Quinone Derivatives as Therapeutics for Lysosomal Storage Disorders

Description of Technology: Novel tocopherol derivatives and tocopheryl quinone derivatives useful in the decrease of lysosomal substrate accumulation, the restoration of normal lysosomal size, and the treatment of lysosomal storage disorders (LSDs) are provided. The inventors have discovered that tocopherol and tocopheryl quinone derivatives with side chain modifications (such as terminal tri-halogenated methyl groups) exhibit improved pharmacokinetics, modulation of mitochondrial potential and restoration of some LSDs phenotypes. These molecules by themselves or in combination with Cyclodextrins (CDs) increase intracellular Ca2+ and enhance exocytosis. Also, the treatment with these compounds reduced the pathological changes in the ultrastructure of LSD cells as observed using electron microscopy analysis. The inventors also found that there is a synergy between CDs and the new tocopherol analogues when tested on the NPC cells and cells from six other

lysosomal storage diseases including Wolman, Niemann Pick Type A, Farber, TaySachs, MSIIIB and CLN2 (Batten) diseases. These new tocopherol analogues are as good or better than natural occurring tocopherols and tocotrienols in reducing cholesterol accumulation in several LSDs.

Potential Commercial Applications: To develop new therapeutics to treat LSDs.

Competitive Advantages:

- The main advantage of the compounds disclosed here is their improved pharmacokinetics.
- The combination of CD and the novel tocopherol analogues may reduce the dosage of each drug and thereby reduce the potential side effects.

Development Stage:

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

Inventors: Juan Jose Marugan, Wei Zheng, Jingbo Xiao, and John McKew (NCATS).

Intellectual Property: HHS Reference No. E–148–2012/0—U.S. Provisional Application No. 61/727,296 filed 16 Nov 2012.

Related Technologies:

- HHS Reference No. E–294–2009/0—PCT Application No. PCT/US2011/044590 filed 19 Jul 2011, which published as WO 2012/012473 on 26 Jan 2012.
- HHS Reference No. E–050–2012/0—US Provisional Application No. 61/679,668 filed 12 Aug 2012.

Licensing Contact: Suryanarayana (Sury) Vepa; 301–435–5020; *vepas@mail.nih.gov*.

Collaborative Research Opportunities: The National Center for Advancing Translational Sciences (NCATS) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Novel Tocopherol and Tocopheryl Quinone Derivatives as Therapeutics for Lysosomal Storage Disorders. For collaboration opportunities, please contact the NCATS Technology Development Coordinator at *NCATSPartnerships@mail.nih.gov*.

Dated: April 23, 2013.

Richard U. Rodriguez,

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

[FR Doc. 2013–09902 Filed 4–25–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

April 23, 2013.

AGENCY: National Institutes of Health, 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.

FOR FURTHER INFORMATION CONTACT: 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.

Device for Non-Surgical Tricuspid Valve Annuloplasty

Description of Technology: This is a non-surgical tricuspid annuloplasty to treat functional tricuspid valve regurgitation, meaning regurgitation with intact valve leaflets. The device is delivered using novel catheter techniques into the pericardial space and positioned along the atrioventricular groove. A compression member is positioned along the tricuspid annular free wall and tension applied through a variably-applied tension element. In the best embodiment, the compression member has an M shaped portion with at least two inflection points between the segments of difference curvatures.

Potential Commercial Applications:

- Valvular heart disease.
- Tricuspid valve annuloplasty.

Competitive Advantages:

- Non-surgical catheter treatment of valve disease.
- Tricuspid valve.

Development Stage:

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

Inventors: Robert Lederman, Kanishka Ratnayaka, Toby Rogers (NHLBI).

Intellectual Property: HHS Reference No. E–027–2013—US Provisional Patent Application 61/785,652 filed 14 Mar 2013.

Related Technologies: HHS Reference Nos. E–112–2010; E–108–2010; E–165–2008; E–249–2006/0,/1,/2.

Licensing Contact: Michael A. Shmilovich, Esq., CLP; 301–435–5019; *shmilovm@mail.nih.gov.*

Collaborative Research Opportunity: The NHLBI is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize technologies for functional tricuspid valve regurgitation. For collaboration opportunities, please contact Peg Koelble at *koelblep@nhlbi.nih.gov.*

Urine-Based Diagnostic Assay for the Early Detection of Cancer

Description of Technology: NIH scientists have identified a panel of metabolite biomarkers capable of predicting the onset of cancer with an accuracy approaching 100%. Concerted changes in the levels of select amino acid, nucleic acid and methylation metabolites in the urine of mice strongly correlated with tumor formation and reflected the progressive derangement in their underlying biochemical pathways. Researchers have developed high-throughput screening methodology to quantify the levels of these metabolites in biological samples for the purposes of assessing cancer risk, determining disease prognosis and monitoring response to therapy. While applicable to many cancers, use of this technology for the detection of colorectal cancer represents a first-in-class diagnostic for this particular disease.

Despite therapeutic advances, colorectal cancer remains a significant clinical burden in terms of morbidity and mortality. Early detection is a key predictor of treatment outcome; however, current diagnostic methods are unsuitable for widespread implementation. The ability to analyze noninvasively obtained patient samples in a high-throughput manner suggests that this technology is well positioned to serve as a population-level screening tool for the early detection of many cancers, including, colorectal.

Potential Commercial Applications:

- A diagnostic screen for the detection of colorectal and other cancers.
- Assay to monitor response to therapy and disease recurrence.

Competitive Advantages: