Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: November 5, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–26793 Filed 11–10–08; 8:45 am]

BILLING CODE 4160–01–S

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 on (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: Data Collection Worksheet Form (DCW): Reinstatement—(OMB No. 0915–0226)

The Data Collection Worksheet Form for the National Health Service Corps Scholarship Program enables the Division of Applications and Awards/Scholarship Branch (DAA/SB) within the Health Resources and Services Administration (HRSA) to obtain the costs charged by each health professions training program for tuition, fees, and other reasonable educational expenses, in order to determine the amount of each scholarship award. The DAA/SB enters this information into its computerized data system, along with the projected amount for the monthly stipend, to determine the amount of each scholarship award.

The estimated annual burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Data Collection Worksheet	650	1	650	0.5	325
Total	650		650		325

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: November 4, 2008.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E8–26816 Filed 11–10–08; 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.

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.

System for Correction of MRI Head Motion

Description of Technology: Motion artifacts continue to be a significant problem in MRI of human brain. Prospective motion correction based on external tracking systems has been proposed to ameliorate this issue. However, the calibration of these systems is very complicated and time consuming, as it requires a camera system calibration as well as a calibration between camera and MRI system using dedicated phantoms. An alternative motion correction method for MRI that does not require calibration and can work with just a single video camera has been developed and is available for licensing. This technology can be broadly applied in MRI to account for motion artifacts in order to improve acquisition time and provide enhanced resolution. This technique will provide a needed method to obtain reliable MRI scans for uncooperative patients (children, seizure patients, etc.)

without the need and expense of multiple scans.

Applications:

- Magnetic Resonance Imaging.
- Diagnostics.

Inventors: Jeff Duyn and Lei Qin (NINDS)

Publications:

1. JH Duyn, P van Gelderen, TQ Li, JA de Zwart, AP Koretsky, M Fukunaga. High-field MRI of brain cortical substructure based on signal phase. *Proc Natl Acad Sci USA*. 2007 Jul 10;104(28):11796–17801.

2. TQ Li, P van Gelderen, H Merkle, L Talagala, AP Koretsky, J Duyn. Extensive heterogeneity in white matter intensity in high-resolution T2*-weighted MRI of the human brain at 7.0 T. *Neuroimage*. 2006 Sep;32(3):1032–1040.

Patent Status: U.S. Provisional Application No. 61/045,782 filed 17 Apr 2008 (HHS Ref. No. E–144–2008/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: John Stansberry, PhD; 301–435–5236; *stansbej@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Neurological Disorders and Stroke—Advanced MRI Section—Laboratory of Functional and Molecular Imaging is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize MRI methods to improve data collection by improved homogeneity, resolution, etc. Please contact Dr. Melissa Maderia at 301–451–3943 or *maderiam@mail.nih.gov* for more information.

Methods for Using Interferon Gamma To Absorb Fluid From the Subretinal Space

Description of Technology: The accumulation of subretinal fluid is associated with certain adverse ocular conditions (including chronic macular edema, age related macular degeneration, and diabetic retinopathy), or retinal injury, or post-surgical complications. Often aberrant proliferation and migration of retinal pigment epithelial (RPE) cells is also associated with these ocular conditions. The RPE is a highly specialized derivative of the neuroectoderm with multiple roles in the maintenance of normal ocular function. Dysfunction of RPE cells has been implicated in inflammatory, degenerative, and dystrophic diseases of the retina and choroid. Interferon gamma (IFNγ) has been implicated in the pathogenesis of a number of intraocular inflammatory diseases of infectious or presumed autoimmune origin. IFNγ has been detected in vitreous aspirates of patients with uveitis, proliferative vitreoretinopathy, and idiophathic inflammatory eye diseases.

The technology provides for methods by which interferon-gamma (IFN-γ) can be used to remove subretinal fluid. The application of INF-γ may be by external application (e.g. eye drops or ointments) or by subretinal injection. The claims in the pending patent application are directed to methods for treating decreases in visual acuity that are associated with diseases that cause the accumulation of fluid in the subretinal space. Additional claims are directed at methods for treating age-related macular degeneration, chronic macular edema, diabetic retinopathy, retinal detachment, or glaucoma that comprise decreasing the amount of fluid present in the subretinal space of patients suffering from such disorders by administering an amount of interferon gamma to the eyes of the patients effective to decrease the amount of fluid present in the subretinal space of the patients.

Applications:

- Treatment and prevention of age-related macular degeneration (AMD), chronic macular edema, diabetic retinopathy, retinal detachment, or glaucoma.
- Treatment of decreases in visual acuity that are associated with diseases that cause the accumulation of fluid in the subretinal space.

Market: Diabetic retinopathy and age-related macular degeneration are the leading causes of blindness for those above age 45 and 60, respectively. These two diseases account for approximately 6–7 million cases of blindness each year in the U.S.

Development Status: Preclinical and animal model studies are in progress.

Inventors: Rong Li, Sheldon S. Miller, and Arvydas Maminishkis (NEI).

Patent Status: U.S. Provisional Application No. 61/089,157 filed 15 Aug 2008 (HHS Reference No. E–169–2008/0–US–01).

Licensing Status: Available for licensing.

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

Collaborative Research Opportunity: The National Eye Institute, Section on Epithelial and Retinal Physiology and Disease, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize methods that activate immune system mediated fluid removal from the distal retina. Please contact John D. Hewes, PhD at 301–435–3121, or *hewesj@mail.nih.gov* for more information.

Retinal Pigment Epithelia-Enriched MicroRNAs To Prevent Cell-Differentiation, Proliferation, and Migration

Description of Technology: The retinal pigment epithelium (RPE) plays a significant role in regulating the microenvironment around the photoreceptors in the distal retina, where the events of phototransduction take place.

Expression profiling of microRNA (miRNAs) in RPE and the adjacent retina and choroid was used to identify six miRNAs enriched in RPE. The potential use of anti-miRNAs specifically directed against miRNA 204 and miRNA 211 to prevent epithelial cell differentiation, proliferation and migration is disclosed. The miRNA 204 and miRNA 211 play a critical role in the control transepithelial electrical resistance. This technology further describes the significance of miRNAs in regulating junctional complexes in epithelial cells.

The claims in the pending patent application are directed towards methods and compositions containing anti-miRNAs or miRNA mimics for preventing or treating detrimental epithelial cell proliferation or loss of epithelial cell differentiation.

Applications:

- Treatment and prevention of age-related macular degeneration (AMD) and proliferative vitreal retinopathy.
- Treatment and prevention of neovascular diseases and carcinoma.

Market: AMD is the most common cause of adult blindness in Western, developed countries. A recent study has estimated that advanced AMD affects about 1.75 million Americans.

Development Status: Preclinical animal model studies and gene knockout studies are in progress.

Inventors: Fei Wang and Sheldon Miller (NEI).

Patent Status: U.S. Provisional Application No. 61/043,330 filed 08 Sep 2008 (HHS Reference No. E–056–2008/0–US–01).

Licensing Status: Available for licensing.

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

Collaborative Research Opportunity: The National Eye Institute, Section on Epithelial and Retinal Physiology and Disease, is seeking statements of capability or interest from parties interested in collaborative research to

further develop, evaluate, or commercialize the use of RPE-specific micro RNAs or anti-miRNAs or miRNA mimics for the treatment and prevention of age-related macular degeneration (AMD) and proliferative vitreal retinopathy and more generally for preventing or treating detrimental epithelial cell proliferation or loss of epithelial cell differentiation, e.g., in the treatment and prevention of neovascular diseases and carcinoma. Please contact John D. Hewes, PhD, at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Human Monoclonal Antibodies Against *Yersinia pestis*

Description of Technology: The technology describes a group of three (3) human monoclonal antibodies directed against the *Yersinia pestis (Y. pestis)* bacterium, the etiologic pathogen of the fatal disease Plague. These antibodies are specifically directed against two of the bacterium's virulent factors, the F1 capsid protein (one antibody) and the low-calcium response antigen V (LcrV) (two antibodies). The antibodies have been shown to provide protection against *Y. pestis* challenge in a mouse model, with the highest protection attained with a combination of all three. The NIH offers the subject antibodies for licensing primarily for the development of therapeutic and/or prophylactic treatment against *Y. pestis* infections. Additionally, the antibodies may find use in research related to the pathogenicity of *Y. pestis* as well as for the development of new treatment against this pathogen.

Although human plague in the United States has occurred as mostly scattered cases in rural areas (an average of 10 to 15 persons each year), and globally, according to the World Health Organization, there are only 1,000 to 3,000 cases of plague every year, it is however of significant importance to develop effective treatment against the plague disease, because of its biodefense significance. *Y. pestis* is included in the CDC and NIH's category A agents that can be readily used as a biological weapon in the hands of bioterrorists.

Applications:

• The antibodies offered for licensing can be used to develop therapeutic and/or prophylactic treatment against *Y. pestis,* the causative pathogen of Plague, which can be readily used as a biological weapon and thus has been considered a category A biodefense agent by the CDC and NIH.

• The antibodies offered for licensing may find use in research related to *Y. pestis* and for development of new treatment against Plague.

Advantages: Currently there is no effective therapeutic or prophylactic treatment available against plague. Antibiotics are primarily used to treat persons infected with *Y. pestis.*

Market:

• Plague, the disease caused by *Y. pestis,* is characterized by symptoms such as fever, chills, cough and difficulty in breathing. If not treated early, the disease can lead to death.

• Although the market size for treating plague is small (1,000 to 3,000 worldwide cases every year and 10 to 15 cases in the United States), a development of effective treatment is of utmost importance as the bacterium can be used as a biological weapon. It is therefore included in the list of category A biodefense agents as defined by the CDC and NIH, and received a significant attention with respect to preparedness against bioterrorism.

Development Status:

• The inventors have demonstrated the protective effectiveness of the antibodies using model mice challenged with the bacterium.

• Further development including clinical trials will be needed to develop the technology to the point of practical application.

Inventors: Dimiter S. Dimitrov (NCI), Xiaodong Xiao (NCI), *et al.*

Relevant Publications:

1. RD Perry and JD Fatherston. Yersinia pestis—etiologic agent of plague. *Clin Microbiol Rev.* 1997 Jan;10(1):35–66.

2. J Hill, SE Leary, KF Griffin, ED Williamson, RW Titball. Regions of Yersinia pestis V antigen that contribute to protection against plague by passive and active immunization. *Infect Immun.* 1997 Nov;65(11):4476–4482.

3. GW Anderson Jr, PL Worsham, CR Bolt, GP Andrews, SL Welkos, AM Friedlander, JP Burans. Protection of mice from fatal bubonic and pneumonic plague by passive immunization with monoclonal antibodies against F1 protein of Yersinia pestis. *Am J Trop Med Hyg.* 1997 Apr;56(4):471–473.

Patent Status: HHS Reference No. E–013–2008—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: The technology is available for non-exclusive licensing under a Biological Materials License Agreement.

Licensing Contact: Uri Reichman, PhD; 301–435–4616; *reichmau@mail.nih.gov*

Collaborative Research Opportunity: The National Cancer Institute CCRNP, Protein Interactions Group, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize human monoclonal antibodies against Yersinia Pestis. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Related Technology: U.S. Patent Application No. 11/944,230 filed 21 Nov 2007 (HHS Reference No. E–189–2007/0), entitled ''Manufacturing Process Improvements for Purification of F1–V as a Vaccine Potentially Protective Against Bubonic and Pneumonic Plague,'' by Steven L. Giardina and David F. Nellis (NIAID)

Viral Inactivation Using Crosslinkers and Detergents

Description of Technology: The subject technology is a method of inactivating enveloped viruses by hydrophobic photoactivatable chemical crossing-linking compounds and detergent treatment. The inactivated viruses may be used as vaccines against the diseases caused by those viruses or as reagents in experimental procedures that require inactivated viral particles. The compounds diffuse into the lipid bilayer of biological membranes and upon UV irradiation will bind to proteins and lipids in this domain, thereby inactivating fusion of enveloped viruses with their corresponding target cells. Furthermore, the selective binding of these chemical crosslinking agents to protein domains in the lipid bilayer may preserve the structural integrity and therefore immunogenicity of proteins on the exterior of the inactivated virus. The additional detergent step effectively eliminates the infectivity of any residual viral particles that are not adequately crosslinked.

Applications:

• Vaccines for enveloped viruses

• Vaccine for Human Immunodeficiency Virus

Advantages:

• Novel method of inactivating enveloped viruses

• May maintain native conformational structures and viral epitopes for generating an effective immune response

Development Status: In vitro data can be provided upon request

Market: Vaccines

Inventors: Julie M. Belanger *et al.* (NCI)

Patent Status:

• U.S. Provisional Application No. 61/025,424 filed 01 Feb 2008 (HHS Reference No. E–331–2007/0–US–01)

• U.S. Provisional Application No. 61/088,294 filed 12 Aug 2008 (HHS Ref. No. E–331–2007/1–US–01)

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Kevin W. Chang, PhD; 301–435–5018; *changke@mail.nih.gov*

Collaborative Research Opportunity: The National Cancer Institute, Center for Cancer Research, Nanobiology Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the use of hydrophobic crosslinkers for their use in vaccine development. Interested collaborators are also invited to provide statements for proposed *in vitro* or *in vivo* studies using various enveloped viruses. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Indoline Compounds for the Treatment of Spinal Muscular Atrophy (SMA) and Other Diseases

Description of Technology: With the goal to treat SMA in patients, several indoline compounds were made and tested for activity. Tests in cells demonstrate that these drugs increased the levels of active SMN protein. This is encouraging since low levels of this protein appears to be the cause of neuronal death that leads to SMA. This class of compounds appears to operate via read-through of a non-sense stop-codon to produce full length, functional protein in SMA models. This mechanism may have utility in several other neurological disorders, including cystic fibroses and Duchene's Muscular Dystrophy.

In addition, these compounds have also been shown to increase the concentration of a glutamate transporter protein in cells, which acts to recover glutamate back into neurons after release. Since the toxic effect of unrecovered excess glutamate is observed in many notorious neurological conditions, these compounds have potential for prevention or treatment.

Applications:

• Treatment of SMA in infants and children.

• Treat genetic-based diseases that result from a premature stop of protein synthesis such as muscular dystrophy and cystic fibrosis.

• Treating or preventing neurological diseases presenting glutamate toxicity like multiple sclerosis, Parkinson's, Alzheimer's, amyotrophic lateral sclerosis (ALS), or others.

Market:

• SMA is a rare genetic disease estimated to affect 1 in 6,000 births and leading genetic cause of death in infants and toddlers.

• Over 25,000 Americans are believed to suffer from SMA and the market size has been estimated between $250 million and $750 million.

Development Status: Pre-clinical, Toxicology and Safety Studies, Animal Models (Dogs and Primates).

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

Related Publication: MR Lunn, DE Root, AM Martino, SP Flaherty, BP Kelley, DD Coovert, AH Burghes, NT Man, GE Morris, J Zhou, EJ Androphy, CJ Sumner, BR Stockwell. Indoprofen upregulates the survival motor neuron protein through a cyclooxygenase-independent mechanism. *Chem Biol.* 2004 Nov;11(11):1489–1493.

Patent Status:

• U.S. Provisional Application No. 60/975,675 filed 27 Sept 2007 (HHS Reference No. E–187–2007/0–US–01);

• PCT Application No. PCT/US2008/077936 filed 26 Sep 2008 (HHS Reference No. E–187–2007/0–PCT–02).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Norbert Pontzer, PhD, JD; 301–435–5502; *pontzern@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 drugs for the treatment of SMA, as well as investigation into novel uses for these indoline compounds. Please contact Dr. Melissa Maderia at *maderiam@mail.nih.gov* or 301–451–3943 for more information.

Discovery of and Use of Fragments of DOC1 as Antiangiogenic and Antitumor Therapy

Description of Technology: This invention describes small cDNA fragments of the coding region for wild type filamin A interacting protein 1-like (FILIP1L), previously known as *down-regulated in ovarian cancer 1-like* (DOC1) and variant 2 of FILIP1L genes that encode proteins that result in the inhibition of cell migration and motility, induce cell apoptosis and inhibit cell proliferation. These effects can be seen on endothelial cells and on tumor cells. These coding sequences have successfully been delivered to endothelial cells and tumor cells both in vitro and in vivo, and have demonstrated significant anti-tumor activity. In addition, the inventors have for the first time expressed the recombinant protein and developed antibodies to detect the protein fragments by Western, ELISA and immunohistochemistry. The significance of this invention is that it could provide for a series of new anti-cancer therapeutics and for the diagnostic means to follow their expression levels.

Applications: This invention could provide new anti-cancer therapeutics and diagnostics.

Market:

• An estimated 1,444,920 new cancer diagnoses in the U.S. in 2007.

• 600,000 deaths caused by cancer in the U.S. in 2006.

• Cancer is the second leading cause of death in the U.S.

• Cancer drug market will likely double to $50 billion in 2010 from $25 billion in 2006.

Development Status: The technology is currently in the pre-clinical stage of development.

Inventors: Steven K. Libutti et al. (NCI).

Relevant Publication: Mijung Kwon et al. Functional characterization of filamin A interacting protein 1-like, a novel candidate for antivascular cancer therapy. *Cancer Res.* 2008 Sep 15;68(18):7332–7341.

Patent Status: U.S. Provisional Application No. 61/005,363 filed 03 Dec 2007 (HHS Reference No. E–166–2007/0-US–01).

Licensing Status: Available for exclusive and non-exclusive license.

Licensing Contact: Adaku Nwachukwu, JD; 301–435–5560; *madua@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute Hatfield Clinical Research Center is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Discovery of and Use of Fragments of DOC1 as Antiangiogenic and Antitumor Therapy. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: November 3, 2008.

Richard U. Rodriguez,

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

[FR Doc. E8–26786 Filed 11–10–08; 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.