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Dated: March 29, 2006.

Robert G. McSwain,

Deputy Director, Indian Health Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Division of Extramural Research and Training; Proposed Collection; Comment Request; Hazardous Waste Worker Training

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Hazardous Waste Worker Training—42 CFR part 65.

Type of Information Collection Request: Revision of OMB No. 0925-0348 and expiration date February 28, 2005.

Need and Use of Information Collection: This request for OMB review and approval of the information collection is required by regulation 42 CFR part 65(a)(6). The National Institute of Environmental Health Sciences (NIEHS) was given major responsibility for initiating a worker safety and health training program under section 126 of the Superfund Amendments and Reauthorization Act of 1986 (SARA) for hazardous waste workers and emergency responders. A network of non-profit organizations that are committed to protecting workers and their communities by delivering high-quality, peer-reviewed safety and health curricula to target populations of hazardous waste workers and emergency responders has been developed. In seventeen years (FY 1987-2004), the NIEHS Worker Training program has successfully supported 20 primary grantees that have trained more than 1.2 million workers across the country and presented over 68,000 classroom and hands-on training courses, which have accounted for

nearly 18 million contact hours of actual training. Generally, the grant will initially be for one year, and subsequent continuation awards are also for one year at a time. Grantees must submit a separate application to have the support continued for each subsequent year. Grantees are to provide information in accordance with S65.4(a), (b), (c) and 65.6(a) on the nature, duration, and purpose of the training, selection criteria for trainees' qualifications and competency of the project director and staff, cooperative agreements in the case of joint applications, the adequacy of training plans and resources including budget and curriculum, and response to meeting training criteria in OSHA's Hazardous Waste Operations and Emergency Response Regulations (29 CFR 1910.120). As a cooperative agreement, there are additional requirements for the progress report section of the application. Grantees are to provide their information in hard copy as well as enter information into the WETP Grantee Data Management System. The information collected is used by the Director through officers, employees, experts, and consultants to evaluate applications based on technical merit to determine whether to make awards.

Frequency of Response: Biannual.

Affected Public: Non-profit organizations.

Type of Respondents: Grantees.

The annual reporting burden is as follows:

Estimated Number of Respondents: 18.

Estimated Number of Responses per Respondent: 2;

Average Burden Hours per Response: 10; and

Estimated Total Annual Burden Hours Requested: 360.

The annualized cost to respondents is estimated at: \$10,764. There are no Capital Costs, Operating costs and/or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use

of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Joseph T. Hughes, Jr., Director, Worker Education and Training Branch, Division of Extramural Research and Training, NIEHS, P.O. Box 12233, Research Triangle Park, NC 27709 or call non-toll-free number (919) 541-0217 or E-mail your request, including your address to wetp@niehs.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: March 27, 2006.

Richard A. Freed,

NIEHS, Associate Director for Management.

[FR Doc. 06-3217 Filed 4-4-06; 8:45 am]

BILLING CODE 4140-01-M

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.

Live Tissue Imaging Gel

Emily Rothstein (NHLBI).

HHS Reference No. E-328-2005/0—
Research Tool.

Licensing Contact: Chekesha Clingman;
301/435-5018;
clingmac@mail.nih.gov.

The National Heart Lung and Blood Institute (NHLBI), Laboratory of Cardiac Energetics, has created a gel with 0.3%–0.5% carbomer 940 which is easily used as an imaging immersion medium for confocal and two photon fluorescence emission microscopy and second harmonic generation imaging. This thick, but transparent, gel can be layered on tissue for microscopic analysis and retain the connection between the objective and tissue at a large working distance without supplementary retention. The thickness of the gel allows for optimal positioning on tissue for imaging in the living animal, which eliminates the frustrations associated with imaging using thinner gels and fluid.

This thick gel can be used by microscopists and pathologists for imaging tissue in a living animal. Also, this gel can be used for skin screening as an alternative to biopsy for image analysis of tissue structure, thus saving diagnosis time and patient discomfort.

The Medusa™ Sequencer: A Sequencing Machine the Size of a Molecule That Could Sequence RNA in a Living Cell

Thomas D. Schneider, Ilya G. Lyakhov, and Danielle Needle (NCI).

U.S. Provisional Application No. 60/749,729 filed December 12, 2005, entitled "Probe for Nucleic Acid Sequencing and Methods of Use" (HHS Reference No. E-194-2005/0-US-01).

Licensing Contact: Cristina Thalhammer-Reyero; 301/435-4507; thalhamc@mail.nih.gov.

Available for licensing and commercial development is the Medusa™ Sequencer, a single-molecule sequencing device that consists of a DNA (or RNA) polymerase attached to a set of four flexible arms. The tip of each arm carries a nonhydrolyzable nucleotide and a spectrally distinct Forster Resonance Energy Transfer (FRET) acceptor fluorophore. A donor fluorophore attached to the polymerase can excite the acceptor fluorophores by FRET. A Medusa™ Sequencer binds to a DNA primer hybridized to the DNA or RNA to be sequenced. The four arms with nucleotide tips "test" the polymerase pocket and the arm that has the nucleotide tip complementary to the unknown base of the sequence will dwell longer than the other three that are not complementary. However, the

polymerase will not incorporate the nucleotide on the tip of the arm into the nascent strand because the nucleotide is nonhydrolyzable. FRET between the donor and the acceptor fluorophore at the arm tip produces a characteristic spectrum that identifies the bound base. Free hydrolyzable dNTPs (or NTPs) allow the Medusa™ Sequencer to step forward. The series of FRET signals reveals the unknown nucleotide sequence. A Medusa™ Sequencer could also be injected into a cell to read mRNA sequences inside a living organism. Coded versions of the Medusa™ Sequencer can signal when the device has been damaged.

The benefits of the Medusa™ Sequencer include: (a) Simplicity, only one reagent required; (b) accuracy for counting individual mRNAs or DNAs; (c) low error rate per base, and this can be improved by modifying the polymerase; (d) speed, a single microscope can be used to obtain many sequences in parallel; (e) exceptionally low cost per sequencing device; and (d) could be used in the clinic along with sequence walkers to analyze patient's genetic diseases (e.g. Medical Applications of Sequence Walkers: ABCR Mutation G863A, <http://www.ccrnp.ncicrf.gov/~toms/g863a.html>).

The technology is further described at <http://www.ccrnp.ncicrf.gov/~toms/patent/medusa>.

The National Institutes of Health, 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 Medusa™ Sequencer. Please contact Melissa Maderia at 301/846-5465 (phone), 301/846-6820 (fax), maderiam@mail.nih.gov (e-mail) for more information.

Nanoprobes for Detection or Modification of Molecules

Ilya G. Lyakhov, Thomas D. Schneider, and Danielle Needle (NCI).

U.S. Provisional Application No. 60/749,858 filed December 12, 2005 (E-195-2005/0-US-01).

Licensing Contact: Cristina Thalhammer-Reyero; 301/435-4507; thalhamc@mail.nih.gov.

Available for licensing and commercial development are the "Rod-tether Nanoprobes", devices consisting of a rigid molecular rod with a flexible molecular tether attached at each end that can be used to detect and/or modify molecules. Each tether tip has a functional group, such as an antibody or oligonucleotide, that recognizes a target

molecule. In addition, one tip carries a donor fluorophore and the other carries an acceptor fluorophore. The fluorophores form a pair for Forster Resonance Energy Transfer (FRET). In the absence of the target molecule, the rod keeps the tether arms apart most of the time, while in the presence of the target molecule, both recognizers bind to the target. This holds the donor and acceptor fluorophores close together. Illumination with light excites the donor and the energy is transferred by FRET to the nearby acceptor, which emits a detectable signal. By reducing an ELISA-like assay entirely to the molecular level, complex macroscopic or microfluidic washing and pumping systems can be eliminated. Rod-tether Nanoprobes can detect a wide variety of clinical and biowarfare reagents. The nanoprobes can also be used to rapidly and simply detect, modify and/or destroy endogenous molecules such as proteins and mRNA involved in a broad range of diseases. The simplest ssDNA-detecting nanoprobe has been created.

The benefits of the Rod-Tether Nanoprobes include: (a) Simplicity, only one reagent required and complicated and expensive microfluidic chips are eliminated (see BioTechniques Jan 2006, 40:1:85-90); (b) reduction of ELISA, Southern, Northern and Western assays to single molecules; (c) speed, only a single molecular reaction is required to detect a target molecule; (d) exceptionally low cost per device; (e) could be used in the clinic to instantaneously analyze patient's blood and detect genetic diseases; and (f) could be used to detect biowarfare agents instantaneously.

The technology is further described at <http://www.ccrnp.ncicrf.gov/~toms/patent/nanoprobe/>.

The National Institutes of Health, 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 Rod-Tether Nanoprobes. Please contact Melissa Maderia at 301/846-5465 (phone), 301/846-6820 (fax), maderiam@mail.nih.gov (e-mail) for more information.

A Novel MRI Adiabatic T₂ Preparation Sequence With Reduced B₁ Sensitivity

Reza Nezafat (NHLBI).

U.S. Patent Application No. 11/147,151 filed June 6, 2005 (HHS Reference No. E-073-2005/0-US-02).

Licensing Contact: Chekesha Clingman; 301/435-5018; clingmac@mail.nih.gov.

This invention relates to a novel magnetic resonance angiography (MRA) method that accomplishes uniform contrast enhancement between coronary arteries and the surrounding tissue across the entire imaging volume. The disclosed technique utilizes an adiabatic refocusing transverse relaxation time (T_2)-preparation pulse sequence, in which the magnetization is tipped into the transverse plane with a hard radio-frequency (RF) pulse and refocused using a pair of adiabatic fast-passage RF pulses. The isochromats are subsequently returned to the longitudinal axis using a hard RF pulse. Simulations and in vivo images acquired with the T_2 -Prep sequence illustrate excellent suppression of artifacts originating from B_1 inhomogeneity while achieving contrast-to-noise (CNR) enhancement between coronary arteries and surrounding tissues. Furthermore, images acquired with the T_2 -Prep sequence show suppression of the banding artifacts and improvement of the visual sharpness of distal segments of the coronaries as compared to images acquired without the T_2 -Prep sequence.

Novel Methods and Compositions for Diagnosing AIDS and Other Diseases Involving Immune System Activation

Gene M. Shearer and Jean-Philippe Herbeuval (NCI).

U.S. Provisional Application No. 60/564,588 filed April 23, 2004 (HHS Reference No. E-045-2004/0-US-01) and U.S. Provisional Application No. 60/634,255 filed December 12, 2004 (HHS Reference No. E-045-2004/1-US-01), combined into PCT/US2005/13554 filed April 21, 2005 (HHS Reference No. E-045-2004/2-PCT-01).

Licensing Contact: Cristina Thalhammer-Reyero; 301/435-4507; thalhamc@mail.nih.gov.

Available for licensing and commercial development are methods and compositions suitable for monitoring the progression of AIDS and other diseases whose progression involves immune system activation in mammals, such as cancer, atherosclerosis, Alzheimer's disease, inflammation, autoimmune disorder, allergic asthma, Crohn's disease, Grave's disease, lupus, multiple sclerosis, Parkinson's disease, allograft transplant rejection, and graft vs. host disease.

In particular, the invention relates to the use of the TRAIL (TNF-related apoptosis-inducing ligand) and TRAIL compounds to monitor the progression of AIDS, and such other diseases. This is accomplished by assessing the presence or concentration of TRAIL,

especially mTRAIL, sTRAIL, the TRAIL DR5 receptor molecule, and biological molecules that activate TRAIL or its receptor. These biological molecules include p53, alpha- and beta-interferon, as well as additional compounds such as CD69 and HLA-DR. Also claimed are kits for immunoassays to determine the presence or concentration of a TRAIL compound in a biological fluid, suitable for determining whether the mammal suffers from any of the above diseases.

TRAIL can be used as a new surrogate biomarker to monitor the progression of HIV infection and other conditions and diseases associated with immune system activation. In the case of HIV infection, measuring levels of this biomarker can distinguish among infected individuals with high viral load, infected individuals with low viral load, and uninfected individuals. Only two surrogate markers are currently recognized by the Food and Drug Administration as clinically relevant to HIV progression, HIV viral load and the absolute number of peripheral CD4+ T cells. Tests for assessing HIV viral load employ PCR, the use of which has drawbacks, including cross-contamination. TRAIL has mechanistic implications for HIV-1 pathogenesis and directly correlates to viral load but not necessarily inversely with CD4+ T cell count. Other surrogate markers have been proposed but do not consistently reflect AIDS progression in all individuals or may result in overlooking possible treatments that may affect disease progression but do not affect the chosen marker. Therefore, use of this new biomarker to assess disease progression in infected individuals and to evaluate the effectiveness of various treatment regimens has several advantages over currently used methods, since TRAIL is a death molecule involved in CD4+ T cell depletion in HIV/AIDS. TRAIL, its receptor, and activating molecules can all be used as sensitive markers for CD4 T cell activation and apoptosis.

The technology is further described at:

1. Herbeuval JP, Hardy AW, Boasso A, Anderson SA, Dolan MJ, Dy M, Shearer GM. Regulation of TNF-related apoptosis-inducing ligand on primary CD4+ T cells by HIV-1: role of type I IFN-producing plasmacytoid dendritic cells. *Proc Natl Acad Sci U S A*. September 27, 2005;102(39):13974-9.

2. Herbeuval JP, Grivel JC, Boasso A, Hardy AW, Chougnet C, Dolan MJ, Yagita H, Lifson JD, Shearer GM "CD4+ T-cell death induced by infectious and noninfectious HIV-1: role of type 1 interferon-dependent, TRAIL/DR5-

mediated apoptosis" *Blood*. November 15, 2005;106(10):3524-31.

3. Herbeuval JP, Boasso A, Grivel JC, Hardy AW, Anderson SA, Dolan MJ, Chougnet C, Lifson JD, Shearer GM "TNF-related apoptosis-inducing ligand (TRAIL) in HIV-1-infected patients and its in vitro production by antigen-presenting cells" *Blood*. March 15, 2005;105(6):2458-64.

Vessel Delineation in Magnetic Resonance Angiographic Images

Peter Yim (CC).

U.S. Patent No. 7,003,144 issued February 21, 2006 (HHS Reference No. E-229-1999/0-US-04).

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

This invention relates to advances in magnetic resonance angiography (MRA) or the imaging of blood vessels in the body for the evaluation of vascular pathology. Presented are new methods for processing magnetic resonance angiographic images, or angiograms, to delineate certain vessels in an angiogram. These methods find particular utility in highly vascular regions of the body such as the cerebrum, heart, abdomen and extremities where there is extensive overlapping and variation in the size of the vessels. Current MRA methods are unable to generate high-resolution images of complex vessel geometries in these dynamic environments. The patent application for this invention covers algorithms and computer-implemented methods for tracking the paths of vessels in magnetic resonance angiography. Also covered are similar methods for digital image processing in alternative imaging technologies such as tomography and X-ray angiography.

Dated: March 28, 2006.

Steven M. Ferguson,

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

[FR Doc. E6-4869 Filed 4-4-06; 8:45 am]

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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. Appendix 2), notice is hereby given of the following meeting.