

regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

Dated: June 23, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03-16954 Filed 7-3-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the

Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: HRSA Grantee Telecommunications and Telehealth Inventory and Database—New

The Health Resources and Services Administration's (HRSA) mission is to improve and expand access to quality health care for all. Through its grant program, HRSA provides funds to ensure the availability of quality health care to low income, uninsured, isolated, vulnerable and special needs populations.

Within HRSA, the Office for the Advancement of Telehealth (OAT) increases access to quality health care services for the underserved by promoting the use of advanced telecommunications and information technologies by health care providers across America. HRSA is a leading national supporter and developer of telehealth, which is the use of electronic information and telecommunications technologies for a wide variety of health-related activities. These include long-distance clinical care, patient and professional education, and health administration.

HRSA provides grant funding to over 8000 recipients to improve healthcare delivery in the United States. Those offices and programs increasingly depend on the emerging technologies and telecommunications systems to deliver healthcare, yet no data is available on grant recipients' access to or utilization of those technologies. The proposed inventory will serve as a model for collecting this type of information across a disparate group of projects nationally and if successful will be ultimately integrated into HRSA's overall data system.

All grantees will be asked to address access to telehealth technologies at their respective institutions. Telehealth activities include the practice of telemedicine, delivery of distance education, health informatics, healthcare staff supervision from remote sites, and the provision of consumer health information using telecommunications technologies. Additionally, grantees will be asked to provide information on their network members or satellite site. For those grantees practicing telemedicine, the survey will include a section on diagnostic tools and clinical capabilities.

The survey will be delivered via the world wide web; hard copy will be made available for those grantees with no Internet access. Substantive questions may be systematically included in the grantees' progress reporting.

Estimated burden hours:

Task	Number of respondents	Number of responses per respondent	Total Number of responses	Hours per response	Total burden hours
Inventory assessment tool—Grant support	100	1	100	.5	50
Inventory assessment tool—No grant support	7,900	1	7,900	.17	1,343
Total	8,000	8,000	1,393

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Allison Eydt, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number 202-395-6974.

Dated: June 27, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03-16955 Filed 7-3-03; 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, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies 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.

Computer Based Model for the Identification and Characterization of Noncompetitive Inhibitors of the Nicotinic Acetylcholine Receptors and Related Ligand Gated Ion Channels

I. W. Wainer (NIA), K. Jozwiak (NIA), S. Ravichandran (SAIC-Frederick), and J. R. Collins (SAIC-Frederick)

DHHS Reference No. E-158-2003/0
filed 11 Apr 2003

Licensing Contact: Cristina

Thalhammer-Reyero; 301/435-4507;
thalhamc@mail.nih.gov.

NIH announces a method for the rapid determination and characterization of noncompetitive inhibitors for nicotinic acetylcholine receptors (nAChR) and other ligand gated ion channels, to be used in drug discovery and development. Furthermore, inhibitors for AChRs are described, which form a large and chemically heterogeneous group of compounds that block the receptor. Inhibitors of AChRs affect a large variety of physiological processes and many are used for therapeutic purposes in different areas.

Classical methods for the identification and characterization of noncompetitive inhibitors are time consuming and not effective in rapid screening of chemical libraries for potential new drug candidates, nor can they be routinely used in the new drug development process. This invention describes the first computer-based model of the inner lumen of a ligand gated ion channel, as well as unique, previously unidentified and unexpected binding pockets. This method allows for computer simulated structures of the members of chemical libraries to be interacted with the computer-based model of the ligand gated channel and the simulation used to predict and describe the pharmacological importance of the interaction, and to screen for unexpected interactions and toxicities of a drug candidate due to off-target interactions.

Ligand gated ion channels are currently one of the largest targets for drug discovery in the pharmaceutical industry. The Ligand Gated Ion Channel superfamily is separated into the nicotinic receptor superfamily (muscular and neuronal nicotinic, GABA-A and C, glycine and 5-HT₃ receptors), the excitatory amino acid superfamily (glutamate, aspartate and kainate receptors) and the ATP purinergic ligand gated ion channels. These families only differ in the number of transmembrane domains found in each subunit.

This work is partially described in Jozwiak *et al.*, "Displacement and non-linear chromatographic techniques in the investigation of the interaction of noncompetitive inhibitors with an immobilized $\alpha 3\beta 4$ nicotinic acetylcholine receptor liquid chromatographic stationary phase," *Anal. Chem.* 74:4618-4624, 2002.

HeadWave Clinical Coil Designed for Magnetic Resonance Elastography

David Moore and Seth Goldstein
(NINDS)

DHHS Reference No. E-041-2003/0
filed 27 Mar 2003

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

The invention is a novel device for measuring the elasticity of cranially encased tissue. The device is a vibrator coil for use in magnetic resonance elastography (MRE). The vibrator coil is applied to the skull of a human patient using a transcranial Doppler monitoring harness and applies mechanical and acoustic waves through the skull. The propagation of the acoustic wave through brain tissue, coupled to phase alteration of voxel isochromats in the presence of applied motion encoding magnetic field gradients permits the measuring of intracranial tissue elasticity.

HTLV-1 p30^{II} and p12^I Proteins as Therapeutic Targets in HTLV-1 Infected Individuals

Genoveffa Franchini and Christophe Nicot (NCI)

DHHS Reference No. E-173-2001/0
filed 19 Aug 2002

Licensing Contact: Sally Hu; 301/435-5606; e-mail: hus@mail.nih.gov.

The invention provides methods that use the HTLV-1 protein p30^{II} for identification of new drugs able to contain expansion of HTLV-1 virus infected cells and methods of using the identified compounds for treating patients with retroviral infection. The present invention is based upon discovery that viral proteins p30^{II} and p12^I are likely essential for the survival of HTLV-1 infected cells. Working in concert these proteins allow the replication of the infected cells while avoiding immune recognition of the host. The data indicate that both p30^{II} and p12^I can be employed as therapeutic targets in containing replication of HTLV-1 infected cells, which in turn will decrease an HTLV-1 infected patient's chance of developing manifestations associated with HTLV-1 infection, e.g., adult T-cell leukemia/lymphoma and tropical

spastic paraparesis/HTLV-1 associated myelopathy.

Methods and Compositions for Inhibiting HIV-Coreceptor Interactions

Oleg Chertov (NCI), Joost J. Oppenheim (NCI), Xin Chen (NCI), Connor McGrath (NCI), Raymond C. Sowder II (NCI), Jacek Lubkowski (NCI), Michele Wetzal (EM), and Thomas J. Rogers (EM)

DHHS Reference No. E-190-2000/0
filed 15 Feb 2001; PCT/US02/05063
filed 15 Feb 2002

Licensing Contact: Sally Hu; 301/435-5606; e-mail: hus@od.nih.gov.

This invention provides peptides that might be potent inhibitors of HIV replication, in both macrophages and T lymphocytes. Specifically, the inventors have identified peptides, from the HIV-1 gp120 envelope protein, that share structural similarities with chemokines and are shown to block "docking" interactions between the HIV-1 envelope protein gp120 and chemokine receptors that function as "coreceptors" for HIV entry on the surface of target cells (macrophages and T lymphocytes). The inventors synthesized two peptides (designated 15K and 15D) based on this information and showed that both were effective in competing with chemokines for binding to CCR5- and CXCR4-expressing cells. These peptides efficiently inhibited infection of human monocyte derived macrophages and peripheral blood mononuclear cells by different strains of HIV. The synthesized peptides also inhibited monocyte chemotaxis stimulated by the chemokine RANTES. Thus, these peptides and other molecules based on their structure can be potentially used as inhibitors of HIV. Moreover, these peptides could also have anti-inflammatory and anti-tumor activity. Further, it has been determined that these peptides are multi-tropic in their effects (blocking HIV interactions with multiple co-receptors) for blocking both T cell tropic (lymphotropic) and macrophage tropic (m-tropic) HIV strains.

3-D Video Image-Based Microscopic Precision Robotic Targeting

Jeffrey C. Smith (NINDS), James W. Nash (EM)

DHHS Reference No. E-162-2000/0
filed 22 Dec 2000

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

The invention is a robotic software and hardware system that allows a microscopic object such as a living biological cell to be targeted in 3-D

optical space for micromanipulation or probing (e.g., drug testing, transgenic manipulation, nucleation/anucleation). The software permits the selection of an object for targeting by a point and click operation with a computer mouse, and performs the transforms between video pixel space, optical space and micro-manipulator mechanical coordinate space to translate the point and click operation into the precision targeting movements of the micro-positioner. The object is viewed in real time through a microscope system via a video output camera and displayed on a computer terminal.

Applications include a variety of biological laboratory precision tools such as positioning of microelectrodes for electrophysiological recording from living cells, micro-injection and micro-manipulation of cells and micro-delivery of pharmacological agents to cells for drug testing and diagnostics.

The invention may also find application in microelectronics fabrication.

Dated: June 27, 2003.

Steven M. Ferguson,

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

[FR Doc. 03-17077 Filed 7-3-03; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, July 2, 2003, 10 a.m. to July 2, 2003, 11:30 a.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on June 20, 2003, 68 FR 37011-37012.

The meeting will be held on July 23, 2003. The time and location remain the same. The meeting is closed to the public.

Dated: June 27, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03-17071 Filed 7-3-03; 8:45 am]

BILLING CODE 4140-01-M

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. appendix 2), 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, ELSI and Genetics.

Date: July 9, 2003.

Time: 3 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 2204, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Cheryl M. Corsaro, Ph.D., Scientific Review Administrator, Genetic Sciences IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2204, MSC 7890, Bethesda, MD 20892, (301) 435-1045, corsaroc@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1 VACC 11: Small Business-Biodefense Vaccines.

Date: July 11, 2003.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Mary Clare Walker, Ph.D., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5104, MSC 7852, Bethesda, MD 20892, (301) 435-1165.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, DBBD F-31 SEP.

Date: July 15, 2003.

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

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street, NW., Washington, DC 20036.

Contact Person: Neal B. West, Ph.D., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, MSC 7808, Bethesda, MD 20892-7808, (301) 435-2514, westnea@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business.

Date: July 15, 2003.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Four points by Sheraton Bethesda, 8400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Joseph Kimm, Ph.D., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5178, MSC 7844, Bethesda, MD 20892, (301) 435-1249.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1 IFCN-6 (02) Bioengineering Study Section.

Date: July 15, 2003.

Time: 12 p.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Four points by Sheraton Bethesda, 8400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Joseph Kimm, Ph.D., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5178, MSC 7844, Bethesda, MD 20892, (301) 435-1249.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: AIDS and Related Research Integrated Review Group, AIDS Immunology and Pathogenesis Study Section.

Date: July 17-18, 2003.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Mayflower Hotel, 1127 Connecticut Avenue NW., Washington, DC 20036.

Contact Person: Abraham P. Bautista, MS, MSC, Ph.D., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5102, MSC 7852, Bethesda, MD 20892, (301) 435-1506, bautista@csr.nih.gov.

Name of Committee: AIDS and Related Research Integrated Review Group, AIDS Molecular and Cellular Biology Study Section.

Date: July 17-18, 2003.

Time: 8 a.m. to 5 p.m.