

Dated: February 7, 2002.  
**Margaret M. Dotzel,**  
*Associate Commissioner for Policy.*  
 [FR Doc. 02-3615 Filed 2-13-02; 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, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to 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, call the HRSA Reports Clearance Officer on (301) 443-1129. *Comments are invited on:* (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (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: The Sentinel Centers Network (SCN) Core Data Set—NEW**

HRSA's Bureau of Primary Health Care (BPHC) established the Sentinel Centers Network (SCN) to assist in addressing critical policy issues. Twenty-five BPHC supported health centers and NHSC sites have been awarded funds through sub-contracts in this first year of operation. These health centers were identified as having

adequate infrastructure and commitment through the competitive contract process to serve as "laboratories" that will generate data for timely policy analyses and conducting projects on topics that have immediate policy impact.

A protocol for core data collection and retrieval, timelines, expectations, and evaluation of the Network sites is currently underway. It is expected that sites will submit these core data, or have these data extracted from their existing information systems periodically. These core data may include provider level, encounter level, and user level information regarding, for example, data on service delivery, utilization, payer sources, demographics, clinical diagnoses and outcomes, staffing, and costs. Since all data obtained from the participant sites will be extracted/compiled from existing information systems, and not through primary data collection, burden will therefore be minimized. In addition, each participant site will receive technical assistance both on site and via telephone to reduce burden as much as possible.

Estimated burden hours:

Type of respondent	Number of respondents	Responses per respondent	Total responses	Hours per responses	Total burden hours
Sites .....	25	4	100	8	800

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 11-05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: February 8, 2002.  
**Jane M. Harrison,**  
*Director, Division of Policy Review and Coordination.*  
 [FR Doc. 02-3617 Filed 2-13-02; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**National Advisory Council on Migrant Health Notice of Meeting**

**AGENCY:** Health Resources and Services Administration, HHS.  
**ACTION:** Notice of meeting.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), announcement is made of the following National

Advisory body scheduled to meet during the month of March 2002:  
*Name:* National Advisory Council on Migrant Health.  
*Date & Time:* March 15, 2002; 9:00 a.m. to 5:00 p.m.; March 16, 2002; 9:00 a.m. to 5:00 p.m.  
*Place:* Hilton Washington and Towers Hotel, 1919 Connecticut Avenue, NW., Washington, DC 20009. Phone: (202)483-3000; Fax (202)232-0428.  
 The meeting is open to the public.  
*Agenda:* This will be a meeting of the Council. The agenda includes an overview of general Council business activities and priorities. Topics of discussion will include development of the Year 2002 recommendations and background statements. In addition, the Council will explore the area of mental health and migrant and seasonal farmworkers. Finally, the Council will be reviewing nominations for Council membership for terms beginning November 2002. The Council meeting is being held in conjunction with the National Association of Community Health Centers, 27th Annual Policy and Issues Forum.  
 Anyone requiring information regarding the subject Council should contact Margaret Davis, Migrant Health Program, staff support to the National Advisory Council on Migrant Health, Bureau of Primary Health Care, Health Resources and Services

Administration, 4350 East-West Highway, Bethesda, Maryland 20814, Telephone 301/594-0291.  
 Agenda items are subject to change as priorities indicate.

Dated: February 8, 2002.  
**Jane M. Harrison,**  
*Director, Division of Policy Review and Coordination.*  
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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, 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.

#### **Filtration of Red Blood Cells**

David F. Stroncek (CC), Susan F. Leitman (CC), Herb M. Cullis (EM), DHHS Reference No. E-339-01/0 filed 06 Nov 2001,

Licensing Contact: Dale Berkley; 301/496-7735 ext. 223; e-mail: [berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov).

The invention is a method for collecting whole blood using an oxygen permeable collection bag to prevent the polymerization of Hemoglobin S, so as to prevent clogging of leukocyte reduction filters. Red blood cell components collected for transfusion are prepared from whole blood collected by phlebotomy or apheresis from healthy volunteers. Before the manufacturing of RBC components is complete, the blood is passed through leukocyte reduction filters to remove contaminating white blood cells. Unfortunately, RBC components from healthy donors with sickle cell trait clog these filters. When this occurs, the RBC components cannot be processed further and must be thrown out. The invention takes advantage of the discovery that the obstruction of leukocyte reduction filters is due to the polymerization of Hemoglobin S in RBCs from people with sickle cell trait when the oxygen concentration is low. The invention demonstrates that collecting the blood in oxygen permeable containers prevents this polymerization, allowing for efficient high-speed filtration of collected blood.

#### **Discovery of Novel Inhibitors of HIV-1 Integrase That Can Be Used for the Treatment of Retroviral Infection Including AIDS**

Terrence R. Burke, Jr., Xuechen Zhang, Godwin C. G. Pais, Christophe Marchand, Evgenia Svarovskaia, Vinay K. Pathak, and Yves Pommier (NCI), DHHS Reference No. E-317-01/0 filed 07 Dec 2001, Licensing Contact: Sally

Hu; 301/496-7056 ext. 265; e-mail: [hus@od.nih.gov](mailto:hus@od.nih.gov).

This invention provides azido group-containing diketo acids that can inhibit HIV-1 integrase in vitro efficiently while being highly selective for the strand transfer step of the integration reaction. Human Immunodeficiency Virus (HIV) and other retroviruses require three viral enzymes for replication: reverse transcriptase, protease and integrase. The prognosis of AIDS has been improved recently by the discovery and application of reverse transcriptase and protease inhibitors. However, a significant fraction of patients fail to respond to such treatments and viral resistance remains a major problem. Furthermore, anti-AIDS combinations are often not well tolerated. Thus, HIV integrase is a rational target for AIDS therapy because genetic studies demonstrated that the enzyme is essential for viral replication while being without a cellular equivalent. Therefore, specific integrase inhibitors should be effective and devoid of toxicity. Since this invention involves the discovery of novel HIV-1 integrase inhibitors that are derived from diketo acids with a different anti-HIV mechanism from that of reverse transcriptase and protease inhibitors, these azide group-containing compounds may represent potential new therapeutics for treatment of retroviral infections, including AIDS.

#### **Strategies To Destabilize the Active HIV-1 Protease Dimer Resulting in Stable Monomer Formation**

John L. Medabalimi (NIDDK), Rieko Ishima (NIDCR), and Angela Gronenborn (NIDDK), DHHS Reference No. E-242-01/0 filed 23 Aug 2001, Licensing Contact: Sally Hu; 301/496-7056 ext. 265; e-mail: [hus@od.nih.gov](mailto:hus@od.nih.gov).

Upon maturation from its precursor, the HIV-1 protease forms and exists mostly as a functional dimer. The present invention relates to compositions and methods for inhibiting activity of functional dimeric retroviral proteases. More specifically, the invention relates to defining specific interface regions critical for dimer formation and production of stable folded monomers. These monomers are inactive and some of these monomers can block functional protease dimerization. The invention also describes a method of designing folded protease monomers that are stable in solution at concentrations several-fold higher than encountered in nature (stable up to 0.6 mM for several weeks at 20° C). Modifying the native protease monomer chain through substituting amino acids at the terminal regions

brings about this stabilization.

Knowledge of unique regions critical for the dimerization of the protease and the stable monomers may be used in the development of novel inhibitors targeting the protease, in the generation of clinically relevant antibodies and anti-idiotypic antibodies for the inhibition of functional protease activity, in the generation of a screening assay or kit that can be used to identify other similarly acting protease antagonists, in the preparation of vaccine formulations, and in the treatment of virally infected cells.

#### **Novel Broadly Reactive HIV-Neutralizing Human Monoclonal Antibody Against Receptor-Induced Epitope on gp120**

Dimiter Dimitrov (NCI), Maxime Moulard (EM), Dennis Burton (EM), Yuuei Shu (NCI), Sanjay Phogat (NCI), and Xiadong Xiao (NCI), DHHS Reference No. E-130-01/0 filed 16 Oct 2001, Licensing Contact: Sally Hu; 301/496-7056 ext. 265; e-mail: [hus@od.nih.gov](mailto:hus@od.nih.gov).

This invention provides a novel anti-HIV human monoclonal antibody named X5. The X5 antibody demonstrates promise over other conventional anti-HIV antibodies because this antibody presents a unique binding activity different than its counterparts. It has been established that the very initial stage of HIV-1 entry into cells is mediated by a complex between the virus envelope glycoprotein (Env) such as gp120-gp41, a receptor CD4 and a co-receptor CCR5. The X5 antibody binds to an epitope on gp120 that is induced by interaction between gp120 and the receptor CD4 and enhanced by the co-receptor CCR5. The X5 antibody also shows strong activity at very low levels (in the range from 0.0001-0.1 Mg/ml concentration in dependence on the isolate). Because it is a human antibody, it can be administered directly into patients so that it is an ideal candidate for clinical trials. It also can be easily produced because it was obtained by screening of phage display libraries and its sequence is known. Finally, since it has neutralized all virus envelope glycoproteins, including from primary isolates from different clades, that were tested against, the epitope is very conserved and resistance is unlikely to develop. Therefore, this antibody and/or its derivatives including fusion proteins with CD4 are good candidates for clinical development.

Additional information on the current research in Dr. Dimitrov's laboratory may be found at <http://www->

[lecb.ncifcrf.gov/~dimitrov/dimitrov.html](http://lecb.ncifcrf.gov/~dimitrov/dimitrov.html).

Dated: February 7, 2002.

**Jack Spiegel,**

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

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant Of Exclusive License: Prophylactic and/or Therapeutic Vaccine Against Pseudomonas aeruginosa, Chlamydia trachomatis and Mycoplasma pneumoniae, Influenza virus, Nisseria gonorrhoea and Vibrio cholerae**

**AGENCY:** National Institutes of Health, Public Health Service, DHHS.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 15 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of a limited field of use exclusive worldwide license to practice the inventions embodied in: U.S. Provisional Patent Application Serial Number 60/257,877, filed December 21, 2000, entitled "A Chimeric Protein Comprising Non-Toxic Pseudomonas Exotoxin A and Type IV Pilin Sequences"; U.S. Patent Number 5,869,608 issued February 9, 1999, entitled "Nucleotide and Amino Acid Sequences of the Four Variable Domains of the Major Outer Membrane Proteins of Chlamydia Trachomatis"; U.S. Patent Application Serial Number 09/247,137 filed February 9, 1999, entitled "Nucleotide and Amino Acid Sequences of the Four Variable Domains of the Major Outer Membrane Proteins of Chlamydia trachomatis"; U.S. Patent Number 4,892,827 issued January 9, 1990, entitled "Recombinant Pseudomonas Exotoxins: Construction of an Active Immunotoxin with Low Side Effects"; U.S. Provisional Patent Application 60/160,923 filed October 22, 1999, entitled "Delivery of Proteins Across Polar Epithelial Cell Layers"; and U.S. Patent Number 5,328,984 issued July 12, 1994, entitled "Recombinant Chimeric Proteins Deliverable Across Cellular Membranes into Cytosol of Target Cells" to Trinity BioSystems, L.L.C. of Los Altos Hills, California, U.S.A. The United States as represented by the Department of Health

and Human Services is an assignee of these patent rights.

**DATES:** Only written comments and/or applications for a license, which are received by the NIH Office of Technology Transfer on or before April 15, 2002, will be considered.

**ADDRESSES:** Requests for a copy of these patent applications, inquiries, comments, and other materials relating to the contemplated license should be directed to: Carol A. Salata, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 496-7735 ext 232; Facsimile: (301) 402-0220; E-mail: [salatac@OD.NIH.GOV](mailto:salatac@OD.NIH.GOV).

**SUPPLEMENTARY INFORMATION:** The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. It is anticipated that this license may be limited to the field of use as a prophylactic and/or therapeutic vaccine against Pseudomonas aeruginosa, Chlamydia trachomatis, Mycoplasma pneumoniae, Influenza virus, Nisseria gonorrhoea and Vibrio cholerae. Trinity BioSystems will use Pseudomonas exotoxin A to target and deliver pathogen Type IV pilin peptide epitopes wherein said pathogen peptide epitopes are inserted into or replace a domain of Pseudomonas exotoxin A. This prospective exclusive license may be granted unless within 60 days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

The patent Application Serial Number 60/257,877 describes a chimeric protein wherein key sequences from a Type IV pilin protein are inserted into a non-toxic version of Pseudomonas aeruginosa exotoxin A. This invention provides candidate chimeric vaccines that generate antibodies that interfere with adherence of Pseudomonas aeruginosa exotoxin A to epithelial cells and neutralize the cytotoxicity of exotoxin A. U.S. Patent Number 5,869,608 and U.S. Patent Application Serial Number 09/247,137 relate to Chlamydia epitopes needed for the Chlamydia vaccine. U.S. Provisional Patent Application Number 60/160,923 provides methods for parenteral administration of a protein by transmucosal delivery and without injection. U.S. Patent Number 4,892,827 describes Pseudomonas exotoxins with a deletion in the Ia domain that makes them less toxic. U.S. Patent Number

5,328,984 contains claims relating to the chimeric Pseudomonas exotoxin protein compositions.

Applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: February 7, 2002.

**Jack Spiegel,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer.*

[FR Doc. 02-3567 Filed 2-13-02; 8:45 am]

BILLING CODE 4140-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Center for Substance Abuse Prevention; Notice of Meeting**

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Center for Substance Abuse Prevention (CSAP) Drug Testing Advisory Board to be held in March 2002.

A portion of the meeting will be open and will include a Department of Health and Human Services drug testing program update, a Department of Transportation drug testing program update, and an update on the draft guidelines for alternative specimen testing and on-site testing. If anyone needs special accommodations for persons with disabilities, please notify the Contact listed below.

The meeting will include developing the final requirements for specimen validity testing that had been published in the **Federal Register** on August 21, 2001 (66 FR 43876), and evaluation of sensitive National Laboratory Certification Program (NLCP) internal operating procedures and program development issues. Therefore, a portion of the meeting will be closed to the public as determined by the SAMHSA Administrator in accordance with Title 5 U.S.C. 552b(c)(9)(B) and 5 U.S.C. App.2, 10(d).

A roster of the board members may be obtained from: Mrs. Giselle Hersh, Division of Workplace Programs, 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, MD 20857, Telephone: (301) 443-6014. The transcript for the open session will be available on the following Web site: <http://>