

Final regulations at 45 CFR part 60 set forth these criteria and procedures for information to be reported to and disclosed by the NPDB. Section 60.3 of these regulations defines the terms used in this announcement.

In determining any changes in the amount of the user fee, the Department uses the criteria set forth in section 60.12(b) of the regulations. The Department must recover the full costs of operating the Data Bank through user fees. Paragraph (b) of the regulations states:

“The amount of each fee will be determined based on the following criteria:

a. Use of electronic data processing equipment to obtain information—the actual cost for the service, including computer search time, runs, printouts, and time of computer programmers and operators, or other employees,

b. Photocopying or other forms of reproduction, such as magnetic tapes—

actual cost of the operator's time, plus the cost of the machine time and the materials used,

c. Postage—actual cost, and

d. Sending information by special methods requested by the applicant, such as express mail or electronic transfer—the actual cost of the special service.”

An annual subscription fee of \$3.25 per practitioner will be charged upon enrollment. This fee includes the cost of an initial query, which automatically occurs when a practitioner is first enrolled, and all reports received on the enrolled practitioner over the course of the subscription period of 1 year. The fee was determined through economic analysis of the average annual rate of queries performed by health care entities in relationship to the current query fee that is based on the actual cost for services. The Department will accept payment for the subscription fee from entities via credit card or electronic

funds transfer. When the prototype period concludes, the Department may change the subscription fee. Any changes will be announced through notice in the **Federal Register**.

The periodic query fee remains at \$4.75 per name. The practitioner self-query fee remains at \$8.00. Currently when a periodic query is on one or more physicians, dentists or other health care practitioners, the appropriate fee will be \$4.75 multiplied by the number of individuals about whom the information is requested. Similarly, when a PDS prototype participating entity enrolls one or more physicians, dentists or other health care practitioners, the appropriate fee will be \$3.25 multiplied by the number of individuals whom are enrolled. An individual practitioner may not enroll in PDS. For examples, see the tables below.

| Periodic query method                                     | Fee per name in query | Examples                                     |
|-----------------------------------------------------------|-----------------------|----------------------------------------------|
| Entity query (via) internet with electronic payment ..... | \$4.75                | 10 names in query.<br>10 x \$4.75 = \$47.50. |
| Practitioner Self-query .....                             | 8.00                  | One self-query = \$8.00.                     |
| Proactive disclosure service (PDS) query method           | Fee per name enrolled | Examples                                     |
| Entity query (via) internet with electronic payment ..... | \$3.25                | 10 names in query.<br>10 x \$3.25 = \$32.50. |

Dated: March 1, 2007.

**Elizabeth M. Duke,**

*Administrator.*

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**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.

#### Novel System for HIV-1 Vaccine Development

*Description of Technology:* The available technologies describe specific immunogenic peptides, peptide modifications and methods for identifying additional immunogens against HIV-1 surface proteins, gp120 and gp41. Additionally, detailed methods for use of the described

immunogenic peptides in the development of vaccines and diagnostics for HIV-1 are disclosed. The current technologies further include a comprehensive system for immunogen design, comprising *in silico* design coupled to feedback from X-ray crystallography, antigenic analysis, and immunization.

The described methodology demonstrates how to transplant a given HIV-1 epitope recognized by broadly neutralizing antibodies into an appropriate scaffold, while preserving its structure and antigenicity. Conservation of the three dimensional structure may lead to the generation of antibodies with broadly neutralizing characteristics, similar to the template antibody. Such epitope-transplant scaffolds may serve as valuable diagnostics to identify specific serum reactivity against the target HIV-1 epitopes. The subject scaffolding technology may be applied to any virus for which a broadly neutralizing

antibody and its respective epitope has been characterized at the atomic-level.

*Applications:*

1. Immunogens that elicit immune responses to HIV-1.
2. Efficient development of vaccines against HIV-1.
3. Screening tool to isolate antibodies with activities similar to identified template antibody.

*Inventors:* Peter D. Kwong *et al.* (NIAID)

*Publications:*

1. G Ofek, W Schief, J Guenaga, *et al.* Epitope-transplant scaffolds: Automated design, structural analysis, and antigenic characteristics. Manuscript in preparation (2007).

2. T Zhou, L Xu, B Dey, AJ Hessel, DV Ryk, SH Xiang, X Yang, MY Zhang, MB Zwick, J Arthos, DR Burton, DS Dimitrov, J Sodroski, R Wyatt, GJ Nabel, PD Kwong. Structural definition of a conserved neutralization epitope on HIV-1 gp120. *Nature*. 2007 Feb 15;445(7129):732-737.

3. DC Douek, PD Kwong, GJ Nabel. The rational design of an AIDS vaccine. *Cell*. 2006 Feb 24;124(4):677-681.

4. G Ofek, M Tang, A Sambor, H Katinger, JR Mascola, R Wyatt, PD Kwong. Structure and mechanistic analysis of the anti-HIV-1 antibody 2F5 in complex with its gp41 epitope. *J Virol*. 2004 Oct;78(19):10724-10737.

*Patent Status:*

1. PCT Application No. PCT/US2005/016633 filed 13 May 2005, which published as WO 2005/111079 on 24 Nov 2005 (HHS Reference No. E-218-2004/0-PCT-02), and National Stage filed in the U.S. on 26 Nov 2006 (HHS Reference No. E-218-2004/0-US-03), entitled "HIV Vaccine Immunogens and Immunization Strategies to Elicit Broadly-Neutralizing Anti-HIV-1 Antibodies Against the Membrane Proximal of HIV gp41".

2. PCT Application No. PCT/US2006/034681 filed 06 Sep 2006 (HHS Reference No. E-324-2005/3-PCT-01), entitled "Conformationally Stabilized HIV Envelope Immunogens and Triggering HIV-1 Envelope to Reveal Cryptic V3-Loop Epitopes"

3. PCT Application No. PCT/US2006/034882 filed 06 Sep 2006 (HHS Reference No. E-280-2006/1-PCT-01), entitled "HIV gp120 Crystal Structure and Its Use to Identify Immunogens"

4. U.S. Provisional Application No. 60/840,119 filed 25 Aug 2006 (HHS Reference No. E-302-2006/0-US-01), entitled "Epitope-Transplant Scaffolds and Their Use"

*Licensing Availability:* Available for non-exclusive or exclusive licensing.

*Licensing Contact:* Susan Ano, Ph.D.; 301/435-5515; [anos@mail.nih.gov](mailto:anos@mail.nih.gov)

## CCR5-Specific Human Monoclonal Antibodies

*Description of Technology:* The subject invention provides the composition claims related to anti-CCR5 monoclonal antibodies, their fusion protein, conjugates, derivatives, or fragments, DNA sequences encoding such antibodies, host cells containing such DNA sequences, as well as the methods to produce them recombinantly and their pharmacological composition.

It has been demonstrated that the HIV co-receptor CCR5 plays an important role in virus entry. The subject antibodies exhibited neutralization activity against HIV-1 infection by binding to cell associated CCR5 *in vitro*. Moreover, subject antibodies have potentially lower immunogenicity and toxicity, because they are fully human antibodies. Therefore, subject anti-CCR5 antibodies have a potential as a therapeutic and/or prophylactic in combination with other HIV-1 neutralizing antibodies and anti-retroviral drugs.

*Applications:* HIV treatment and prevention.

*Development Status:* *In vitro* data is available at this time.

*Inventors:* Dimitar S. Dimitrov and Mei-Yun Zhang (NCI).

*Related Publications:*

1. C Pastori *et al.* Long-lasting CCR5 internalization by antibodies in a subset of long-term nonprogressors: A possible protective effect against disease progression. *Blood*. 2006 Jun 15;107(12):4825-4833.

2. MY Zhang, B Vu, CC Huang, I Sidirov, V Choudhry, PD Kwong, DS Dimitrov. Identification of human monoclonal antibodies specific for CCR5 from an antibody library derived from HIV-infected long-term non-progressors. *Retrovirology*. 2006 Dec 21;3 Suppl 1:S61.

3. DS Dimitrov. Virus entry: molecular mechanisms and biomedical applications. *Nat Rev Microbiol*. 2004 Feb;2(2):109-122.

*Patent Status:* U.S. Provisional Application No. 60/859,401 filed 15 Nov 2006 (HHS Reference No. E-297-2006/0-US-01)

*Licensing Availability:* Available for exclusive and non-exclusive licensing.

*Licensing Contact:* Sally Hu, Ph.D.; 301/435-5606; [HuS@mail.nih.gov](mailto:HuS@mail.nih.gov).

*Collaborative Research Opportunity:* The NCI CCR Nanobiology Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize monoclonal antibodies. Please contact

John D. Hewes, Ph.D. at 301-435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

Dated: February 28, 2007.

**Steven M. Ferguson,**

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

[FR Doc. E7-3959 Filed 3-6-07; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Office of the Director, National Institutes of Health; Notice of 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 a meeting of the Advisory Committee on Research on Women's Health.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* Advisory Committee on Research on Women's Health.

*Date:* March 29-30, 2007.

*Time:* March 29, 2007, 9 a.m. to 5 p.m.

*Agenda:* Provide advice to the Office of Research on Women's Health (ORWH) on appropriate research activities with respect to women's health and related studies to be undertaken by the National Research Institutes; to provide recommendations regarding ORWH activities; to meet the mandates of the office; and for discussion of scientific issues.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, 6C/10, Bethesda, MD 20892.

*Time:* March 30, 2007, 9 a.m. to 1 p.m.

*Agenda:* Same as above.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, 6C/10, Bethesda, MD 20892.

*Contact Person:* Joyce Rudick, Director, Programs & Management, Office of Research on Women's Health, Office of the Director, National Institutes of Health, Building 1, Room 201, Bethesda, MD 20892, 301/402-1770.

Information is also available on the Institute's/Center's home page: <http://www4.od.nih.gov/orwh/>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research