

2950. The MAbs that are available for licensing are the following: 1129, 1153, 1142, 1200, 1214, 1237, 1112, 1269, and 1243. One of these MAbs, 1129, is the basis for a humanized murine MAb (see U.S. Patent 5,824,307 to humanized 1129 owned by MedImmune, Inc.), recently approved for marketing in the United States. MAbs in the panel reported by Beeler et al. have been shown to be effective therapeutically when administered into the lungs of cotton rats by small-particle aerosol. Among these MAbs several exhibited a high affinity (approximately 10^9M^{-1}) for the RSV F glycoprotein and are directed at epitopes encompassing amino acid 262, 272, 275, 276 or 389. These epitopes are separate, nonoverlapping and distinct from the epitope recognized by the human Fab of U.S. Patent 5,762,905 owned by The Scripps Research Institute.

Applications: Research and drug development for treatment of respiratory syncytial virus.

Inventors: Robert M. Chanock, Brian R. Murphy, Judith A. Beeler, and Kathleen L. van Wyke Coelingh (NIAID).

Patent Status: HHS Reference No. B-056-1994/1—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for non-exclusive licensing under a Biological Materials License Agreement.

Licensing Contact: Peter A. Soukas, J.D.; 301/435-4646; soukasp@mail.nih.gov.

Neutralizing Monoclonal Antibodies to Respiratory Syncytial Virus

Description of Technology:

Respiratory syncytial virus (RSV) is the most common cause of bronchiolitis and pneumonia among infants and children under 1 year of age. Illness begins most frequently with fever, runny nose, cough, and sometimes wheezing. During their first RSV infection, between 25% and 40% of infants and young children have signs or symptoms of bronchiolitis or pneumonia, and 0.5% to 2% require hospitalization. Most children recover from illness in 8 to 15 days. The majority of children hospitalized for RSV infection are under 6 months of age. RSV also causes repeated infections throughout life, usually associated with moderate-to-severe cold-like symptoms; however, severe lower respiratory tract disease may occur at any age, especially among the elderly or among those with compromised cardiac, pulmonary, or immune systems.

This invention is a human monoclonal antibody fragment (Fab) discovered utilizing phage display technology. The neutralizing

monoclonal antibody was isolated and its binding site was identified. Fab F2-5 is a broadly reactive fusion (F) protein-specific recombinant Fab generated by antigen selection from a random combinatorial library displayed on the surface of filamentous phage. In an in vitro plaque-reduction test, the Fab RSVF2-5 neutralized the infectivity of a variety of field isolates representing viruses of both RSV subgroups A and B. The Fab recognized an antigenic determinant that differed from the only other human anti-F monoclonal antibody (RSV Fab 19) described thus far. A single dose of 4.0 mg of Fab RSVF2-5/kg of body weight administered by inhalation was sufficient to achieve a 2000-fold reduction in pulmonary virus titer in RSV-infected mice. The antigen-binding domain of Fab RSVF2-5 offers promise as part of a prophylactic regimen for RSV infection in humans.

Application: Respiratory Syncytial Virus prophylaxis/therapeutic.

Development Stage: The antibodies have been synthesized and preclinical studies have been performed.

Inventors: Brian Murphy (NIAID), Robert Chanock (NIAID), James Crowe (NIAID), et al.

Publication: JE Crowe et al. Isolation of a second recombinant human respiratory syncytial virus monoclonal antibody fragment (Fab RSVF2-5) that exhibits therapeutic efficacy in vivo. *J Infect Dis.* 1998 Apr;177(4):1073-1076.

Patent Status: HHS Reference No. E-001-1996/0—U.S. and Foreign Rights Available.

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

Licensing Contact: Peter A. Soukas, J.D.; 301/435-4646; soukasp@mail.nih.gov.

Human Neutralizing Monoclonal Antibodies to Respiratory Syncytial Virus and Human Neutralizing Antibodies to Respiratory Syncytial Virus

Description of Technology: This invention is a human monoclonal antibody fragment (Fab) discovered utilizing phage display technology. It is described in Crowe et al., *Proc Natl Acad Sci USA.* 1994 Feb 15;91(4):1386-1390 and Barbas et al., *Proc Natl Acad Sci USA.* 1992 Nov 1;89(21):10164-10168. This MAb binds an epitope on the RSV F glycoprotein at amino acid 266 with an affinity of approximately 10^9M^{-1} . This MAb neutralized each of 10 subgroup A and 9 subgroup B RSV strains with high efficiency. It was effective in reducing the amount of RSV in lungs of RSV-infected cotton rats 24 hours after treatment, and successive

treatments caused an even greater reduction in the amount of RSV detected.

Applications: Research and drug development for treatment of respiratory syncytial virus.

Inventors: Robert M. Chanock (NIAID), Brian R. Murphy (NIAID), James E. Crowe Jr. (NIAID), et al.

Patent Status: U.S. Patent 5,762,905 issued 09 Jun 1998 (HHS Reference No. E-032-1993/1-US-01); U.S. Patent 6,685,942 issued 03 Feb 2004 (HHS Reference No. E-032-1993/1-US-02); U.S. Patent Application No. 10/768,952 filed 29 Jan 2004 (HHS Reference No. E-032-1993/1-US-03).

Licensing Status: Available for non-exclusive licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301/435-4646; soukasp@mail.nih.gov.

Dated: September 26, 2008.

Richard U. Rodriguez,

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

[FR Doc. E8-23437 Filed 10-2-08; 8:45 am]

BILLING CODE 4140-01-P

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.

The meeting 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Early Diagnosis Using Nanotechnology-Based Imaging and Sensing.

Date: October 23, 2008.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6116 Executive Boulevard, Room 406, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Joyce C. Pegues, PhD, Scientific Review Officer, Special Review

and Logistics Branch, Division of Extramural Activities, NIH National Cancer Institute, 6116 Executive Boulevard, Room 7149, Bethesda, MD 20892-8329, 301-594-1286, peguesj@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 26, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-23454 Filed 10-2-08; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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: National Institute on Aging Special Emphasis Panel, Sleep, Circadian Function and Cardiometabolic Disease.

Date: October 31, 2008.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, 2C212, Bethesda, MD 20892. (Telephone Conference Call)

Contact Person: Elaine Lewis, PhD, Scientific Review Administrator, Scientific Review Office, National Institute on Aging, Gateway Building, Suite 2C212, MSC-9205, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-402-7707, elainelewis@nia.nih.gov.

Name of Committee: National Institute on Aging Special Emphasis Panel SWAN.

Date: November 3, 2008.

Time: 1:30 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20814. (Telephone Conference Call)

Contact Person: Alicja L. Markowska, PhD, DSC, National Institute on Aging, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301-496-9666, markowsa@nia.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: September 26, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-23445 Filed 10-2-08; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS-2008-0007]

Privacy Act of 1974; Department of Homeland Security Advisory Committees System of Records

AGENCY: Privacy Office; DHS.

ACTION: Notice of Privacy Act system of records.

SUMMARY: In accordance with the Privacy Act of 1974 and as part of the Department of Homeland Security's ongoing effort to review and update legacy system of record notices, the Department of Homeland Security proposes to consolidate two legacy record systems: FEMA/ADM-3-Advisory Committee Files (55 FR 37182 September 7, 1990) and DOT/CG 586 Chemical Transportation Industry Advisory Committee (65 FR 19475 April 11, 2000) into one system, titled Department of Homeland Security Advisory Committees. This system will allow the Department of Homeland Security to collect and maintain information on advisory committee members and applicants. Categories of individuals, categories of records, and the routine uses of these legacy system of records notices have been consolidated and updated to better reflect the Department's advisory committee record systems. This consolidated system will be included in the Department of Homeland Security's inventory of system records.

DATES: Submit comments on or before November 3, 2008.

ADDRESSES: You may submit comments, identified by docket number DHS-2008-0007 by one of the following methods:

- *Federal e-Rulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* 1-866-466-5370.

- *Mail:* Hugo Teufel III, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

- *Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change and may be read at <http://www.regulations.gov>, including any personal information provided.

- *Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: For general questions and privacy issues please contact: Hugo Teufel III (703-235-0780), Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

Pursuant to the savings clause in the Homeland Security Act of 2002, Public Law 107-296, Section 1512, 116 Stat. 2310 (November 25, 2002), the Department of Homeland Security (DHS) and its components and offices have relied on preexisting Privacy Act systems of records notices for the collection and maintenance of records that concern any individual who serves on a DHS-wide and/or component specific advisory committee.

As part of its efforts to streamline and consolidate its records systems, DHS is establishing a new agency-wide system of records under the Privacy Act (5 U.S.C. 552a) for DHS advisory committees. This record system will allow all component parts of DHS to collect and preserve the required personally identifiable information needed for members who apply for or participate in DHS advisory committees. The system will consist of both electronic and paper records and will be used by DHS and its components and offices to maintain records of Federal government employees and other persons who participate in DHS-sponsored Federal advisory committees. The data will be collected by individual name, name of committee, and/or other unique personal identifier. The collection and maintenance of this information will assist DHS in maintaining a list of members of the various Federal advisory committees, internal committees, and interagency committees to provide DHS with information on committee functions,