DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; The Cardiovascular Health Study (CHS)

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval the information collection listed below. This proposal information collection was previously published in the **Federal Register** on March 25, 2004, pages 15346–15347, and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: The Cardiovascular Health Study. *Type of Information Collection Request:* Revision of a currently approved collection (OMB NO. 0925–0334). *Need and Use of Information Collection:* This study will quantify associations between conventional and hypothetical risk factors and coronary heart disease (CHD) and stroke in people age 65 years and older. The primary objectives include quantifying associations of risk factors with subclinical disease; characterize the natural history of CHD and stroke; and identify factors associated with clinical course. The findings will provide important information on cardiovascular disease in an older U.S. population and lead to early treatment of risk factors associated with disease and identification of factors which may be important in disease prevention. *Frequency of Response:* Twice a year (participants) or once per cardiovascular disease event (proxies and physicians). *Affected Public:* Individuals. *Type of Respondents:* Individuals recruited for CHS and their selected proxies and physicians. The annual reporting burden is as follows: *Estimated Number of Respondents:* 3,915; *Estimated Number of Responses per Respondent:* 3.2; *Average Burden Hours Per Response:* 0.21; and *Estimated Total Annual Burden Hours Requested:* 868. The annualized cost to respondents is estimated at $55,633. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

There are no capital, operating, or maintenance costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent *	Average burden hours per response	Estimated total annual burden hours requested
Participants	2,506	3.9	0.21	681
Physicians	380	1.0	0.09	11
Participant proxies	1029	2.3	0.22	176
Total	3,915	3.2	0.21	868

* Total for 3 years.

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.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Jean Olson, NIH, NHLBI, 6701 Rockledge Drive, MSC 7934, Bethesda, MD 20892–7934, or call non-toll-free number (301) 435–0707 or E-mail your request, including your address to: *OlsonJ@nhlbi.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: June 21, 2004.

Peter Savage,

Director, DECA, NHLBI.

[FR Doc. 04–14776 Filed 6–29–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing: SARS-Related Technologies

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

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.

SARS Coronavirus MVA Vaccines and Therapy

Bernard Moss (NIAID).
U.S. Provisional Application No. 60/558,995 filed 05 Apr 2004 (DHHS Reference No. E–165–2004/0–US–01).
Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov.*

Intranasal or intramuscular inoculations of BALB/c mice with modified vaccinia Ankara (MVA) vector encoding SARS–CoV Spike protein produced serum antibodies that recognized SARS S in ELISA and elicited protective immunity as shown by reduced titers of SARS–CoV in the upper and lower respiratory tracts of mice following challenge. Passive transfer of serum from mice immunized with MVA/S to naive mice also reduced the replication of SARS–CoV in the respiratory tract following challenge, demonstrating the role of antibody to S in protection.

Enhanced Sensitivity ELISA for SARS Diagnostic

Gary J. Nabel *et al.* (NIAID).
U.S. Provisional Application No. 60/503,508 filed 15 Sep 2003 (DHHS Reference No. E–334–2003/0–US–01).
U.S. Provisional Application No. 60/550,317 filed 08 Mar 2004 (DHHS Reference No. E–334–2003/1–US–01).
Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov.*

Reagents and protocols for extremely sensitive ELISA for use as a SARS diagnostic are described. The ELISA uses recombinant-expressed nucleoprotein (N) or spike (S) glycoprotein from the SARS coronavirus as capture antigens. As little as five (5) days after onset, detection of antibody response is possible. The ELISA described herein is more sensitive than existing technology because of the N and S proteins; existing ELISAs use formalin-inactivated whole virus or peptides.

E–334–2003/1–US–01 also describes DNA Vaccines (CMV/R–SARS–S plasmid) including a nucleic acid encoding the peptide of SARS Spike glycoprotein, the RSV enhancer, the mouse ubiquitin enhancer (mUBB), and the CMV enhancer (Xu *et al.* 1998 Nature Med. 4: 37–42). Optionally the HTLV–1 R region (Takebe *et al.* 1988 Mol Cell Biol 8: 466–472) is also included.

Interferon-Alpha SARS Treatment

Kathryn C. Zoon, Renqui Hu, Joseph B. Bekisz (NCI).

U.S. Provisional Application filed 30 Apr 2004 (DHHS Reference No. E–278–2003/0–US–01).

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

The Public Health Service seeks a licensee to commercialize protein engineered human interferon alphas for treating and/or preventing a SARS-associated coronaviral infection in humans and other relevant mammalian species.

Soluble SARS Coronavirus Spike Protein (S Protein)

Dimiter S. Dimitrov, Xiadong Xiao (NCI).

U.S. Provisional Application No. 60/489,166 filed 21 Jul 2003 (DHHS Reference No. E–228–2003/0–US–01).

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

The SARS coronavirus is etiologically linked to severe acute respiratory syndrome. Soluble forms of the SARS coronavirus spike protein have been cloned, expressed and characterized, and are available for licensing for use as research reagents, in the development of vaccines and inhibitors of the viral infection, for selection of monoclonal antibodies, and development of kits containing antibodies that bind to the spike protein. The filed patent application additionally claims the associated spike protein polypeptides, peptide fragments, and conserved variants thereof; nucleic acid segments and constructs that encode the spike protein, polypeptides and peptide fragments of the spike protein, and conserved variants thereof and coupled proteins that include the spike protein or a portion thereof and peptidomimetics.

Dated: June 20, 2004.

Steven M. Ferguson,

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

[FR Doc. 04–14750 Filed 6–29–04; 8:45 am]

BILLING CODE 4140–01–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.

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Antibody (Anti-Allergen) Microarray

Jay E. Slater, William J. Finlay, Nicolette DeVore (FDA)
DHHS Reference No. E–044–2004/0—Research Tool
Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov*

Available for licensing as a biological material or by material transfer is a microarray with immobilized antibodies specific to particular allergens or allergen epitopes and specifically allergens from an allergen vaccine or extract. Allergen extracts are manufactured and sold worldwide for the diagnosis and treatment of IgE-mediated allergic disease. Each extract contains a variety of active allergenic components (*e.g.*, proteins, carbohydrates and other small molecules) in varying concentrations and immugenicities. Most allergen extracts are non-standardized. These extracts have been labeled either with a designation of extraction ratio (w/v) or with a protein unit designation determined using the Kjeldahl method (protein nitrogen units/mL). There appears to be little correlation between these two designations and biological measures of allergen potency. At