

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 (OMB), 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: Data System for Organ Procurement and Transplantation Network (42 CFR Part 121, OMB No. 0915-0184): Extension

The operation of the Organ Procurement and Transplantation Network (OPTN) necessitates certain recordkeeping and reporting requirements in order to perform the functions related to organ

transplantation under contract to HHS. This is a request for an extension of the current recordkeeping and reporting requirements associated with the OPTN. These data will be used by HRSA in monitoring the contracts for the OPTN and the Scientific Registry of Transplant Recipients (SRTR) and in carrying out other statutory responsibilities. Information is needed to monitor compliance of member organizations with OPTN rules and requirements, to ensure that all qualified entities are accepted for membership in the OPTN, and to ensure patient safety.

Estimated Annual Reporting and Recordkeeping Burden

Section and activity	Number of respondents	Responses per respondents	Total responses	Hours per response	Total burden hours
121.3(b)(2): OPTN membership requirements for OPOs, hospitals, and histocompatibility laboratories	40	1	40	45	1,800
121.3: Application for Non-Institutional Members	20	1	20	10	200
121.3(b)(4): Appeal for OPTN membership	2	1	2	3	6
121.6(c) (Reporting): Submitting criteria for organ acceptance	900	1	900	0.5	450
121.6(c) (Disclosure): Sending criteria to OPOs	900	1	900	0.5	450
121.7(b)(4): Reasons for Refusal	900	38	34,200	0.5	17,100
121.7(e): Transplant to prevent organ wastage	260	1.5	390	0.5	195
121.9(b): Designated Transplant Program Requirements	10	1	10	5.0	50
121.3: Personnel Change Application	324	1	324	10	3,240
121.9(d): Appeal for designation	2	1	2	6	12
Total	974	39,704	23,503

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to *OIRA_submission@omb.eop.gov* or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: November 29, 2007.

Alexandra Huttinger,
Acting Director, Division of Policy Review and Coordination.

[FR Doc. E7-23538 Filed 12-4-07; 8:45 am]

BILLING CODE 4165-15-P

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 proposed information collection was previously published in the **Federal Register** on September 12, 2007, page 52155, and allowed 60 days for public comment. One comment was 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, any 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 Request:* Reinstatement (OMB No. 0925-0334). *Need and Use of Information Collection:* This study quantifies 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;

characterizing the natural history of CHD and stroke; and identifying factors associated with clinical course. The findings 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 that may be important in disease prevention. OBM clearance is being sought for data collection activities at only one of the four CHS field centers (the Pittsburgh field center), which are expected to end on May 31, 2008. Other data collection efforts in the CHS cohort are supported by various non-contract funding sources. *Frequency of response:* Twice a year (participants) or once per cardiovascular disease event (proxies); *Affected public:* Individuals. *Types of Respondents:* Individuals recruited for CHS and their selected proxies. The annual reporting burden is as follows: *Estimated Number of Respondents:* 467; *Estimated Number of Responses per Respondent:* 1.2; and *Estimated Total Annual Burden Hours Requested:* 281. The annualized cost to respondents is estimated at: \$5,225.

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	346	1.2	0.5	208
Participant proxies	121	1.2	0.5	73
Total	467	1.2	0.5	281

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, Epidemiology Branch, Division of Prevention and Population Sciences, NHLBI, NIH, II Rockledge Centre, 6701 Rockledge Drive, Suite 10018, MSC # 7936, Bethesda, MD 20892-7936, or call 301-435-0397 (non-toll-free number), 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: November 1, 2007.

Mike Lauer,

Director, Division of Prevention and Population Sciences, NHLBI, National Institutes of Health.

Dated: November 20, 2007.

Suzanne Freeman,

OMB Clearance Officer, NHLBI, National Institutes of Health.

[FR Doc. E7-23515 Filed 12-4-07; 8:45 am]

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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, 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.

New Epitopes Recognized by Antibodies Against Human and Avian Influenza for Vaccines and Diagnostic Assays

Description of Technology: Available for licensing and commercial development are intellectual properties drawn to peptides and polypeptides that elicit immunogenic responses in a

mammal; especially neutralizing antibodies, against human and avian influenza strains H1N1, H3N2, H5N1 and H7N7. Materials in the form of immunogenic compositions including these peptides and polypeptides can also be in-licensed along with the patent rights. Pharmaceutical compositions including these peptides and polypeptides with or without adjuvants are within the scope of the invention. Nucleic acids and expression cassettes encoding these peptides and polypeptides are also within the scope of the invention. Methods of inhibiting infection by influenza, with or without cell entry, are also within the scope of the invention using the aforementioned peptides and polypeptides.

Applications: Vaccines; Therapeutics; Diagnostics; Influenza.

Inventors: Hana Golding and Surender Khurana (FDA).

Patent Status: U.S. Provisional Application No. 60/929,119 filed 13 June 2007 (HHS Reference No. E-236-2007/0-US-01).

Licensing Status: Available for licensing.

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

Collaborative Research Opportunity: The FDA/CBER Laboratory of Retrovirus Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Beatrice A. Droke at 301/827-7008 or bdroke@oc.fda.gov for more information.

Trifunctional Imaging Agent for Monoclonal Antibody Tumor-Targeted Imaging

Description of Technology: Available for licensing and commercial development is a novel lysine-based trifunctional chelate which bears both a chelating moiety (CHX-A") for sequestering radiometals (⁸⁶Y or ¹¹¹In) and a near-infrared dye, e.g., Cy5.5, for dual modality PET (or SPECT) and fluorescence imaging. Successful conjugation of monoclonal antibody trastuzumab (Herceptin) or cetuximab (Erbix) has also been achieved by efficient thiol-maleimide chemistry,