

existing measures to fill critical gaps in measures of health care performance.

National Quality Forum, 601 Thirteenth Street, NW., Suite 500 North, Washington, DC 20005, Fax 202-783-3434, <http://www.qualityforum.org>.

### III. Secretarial Comments on the Annual Report to Congress

The Secretary is pleased with the scope and vision of NQF's March 2009 annual report. The contract with this consensus-based entity, NQF, provides a unique opportunity to further enhance HHS' efforts to foster a collaborative, multi-stakeholder approach to increase the availability of national voluntary consensus standards for quality and efficiency measures to ensure broad transparency in achieving value in health care delivery. An internal multidisciplinary cross-component HHS team is working collaboratively with NQF to ensure a clear multi-year vision to ensure the most efficient and effective utilization of the HHS contract. HHS looks forward to the ongoing opportunity to collaborate with the broader health care community as part of this NQF contract to ensure a consensus-based national strategy and priority setting process for health care measurement focusing on high-quality, patient-centered, efficient health care delivery.

### IV. Future Steps

The consensus based contract with NQF is a four year contract. During the first year of the contract, NQF shall complete deliverables for each task. HHS will task NQF with single year and multi-year projects.

#### *Formulation of National Strategy and Priorities for Health Care Performance Measurement*

During the first year of the HHS contract, NQF will create a framework

for measurement prioritization by conducting an environmental scan of at a minimum, the 20 patient conditions that account for over 95% of costs to the Medicare program. NQF is establishing a steering committee to oversee the prioritization process.

#### *Maintenance of Consensus Endorsed Measures*

During the first year of the HHS contract, NQF is maintaining endorsed measures relevant to HHS-wide programs and will be maintaining consensus-based endorsed measures as developed under the priority process.

#### *Promotion of Electronic Health Records*

During the first year of the HHS contract, NQF is supporting the promotion of electronic health records and quality measurement incorporation as part of HHS-wide efforts.

#### *Focused Measure Development, Harmonization, and Endorsement Efforts to Fill Critical Gaps in Performance Measurement*

During the first year of the HHS contract NQF is supporting a variety of performance measurement efforts including, but not limited to, the areas of efficiency, harmonization, outcomes, patient safety, care coordination, ICD-10, palliative care, and nursing home quality metrics.

The public is encouraged to give input through the NQF process and will be able to track the progress on work related to this contract on the NQF Web site located at: <http://www.qualityforum.org/projects/ongoing/hhs/>.

### V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements.

Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Dated: September 3, 2009.

**Kathleen Sebelius,**

*Secretary, Department of Health and Human Services.*

[FR Doc. E9-21783 Filed 9-4-09; 4:15 pm]

**BILLING CODE P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Submission for OMB Review; Comment Request

*Title:* Head Start Program Administrative Practice and Procedure; Appeal Procedures, 45 CFR Part 1303.

*OMB No.:* 0980-0242.

*Description:* Section 646 of the Head Start Act requires the Secretary of Health and Human Services to prescribe a timeline for conducting administrative hearings when adverse actions are taken or proposed against Head Start and Early Head Start grantees and delegate agencies. The Office of Head Start is proposing to renew, without changes, this rule, which implements these requirements and which prescribes when a grantee must submit certain information and what that information shall include.

*Respondents:* Head Start and Early Head Start grantees and Delegate Agencies.

### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Rule .....	20	1	26	520

*Estimated Total Annual Burden Hours:* 520.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the

information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the

proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202-395-7245, Attn: Desk Officer for the Administration for Children and Families.

Dated: September 3, 2009.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. E9-21718 Filed 9-9-09; 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.

#### Use of a Modified Adaptor Molecule LAT to Improve Immunotherapy for Cancer and Other Diseases

*Description of Technology:* One problem with the development of immunotherapy for cancer or other diseases is the inability to stimulate a sufficient immune response in patients to tumor associated antigens. The Linker Adapted for T Cell Signaling molecule (LAT) has been shown to be an important molecule in T cell signaling. The inventions described and claimed in this patent application illustrate a new supportive role for LAT which may be harnessed to improve a patient's immune response to tumor-associated antigens.

A number of approaches to improving the immune response in cancer immunotherapy have been investigated. One such approach is to be able to influence the potency of T Cell Signaling. This invention exploits the role of LAT in T Cell signaling and

provides a means to create a more intense and effective T Cell response. This would have the end result of improving the overall response of a patient's immune system to the presence of tumor-associated antigens.

With T Cell signaling being important in the body's immune response to bacterial and viral antigens it may also be possible to harness the modified LAT molecules to improve the immune response in developing immunotherapy for infectious disease.

#### Applications

- As an adjuvant with immunotherapeutic agents to improve the overall response of a patient's immune system to tumor associated antigens.

- As an adjuvant with immunotherapeutic agents to improve the overall response of a patient's immune system to bacterial associated antigens.

- As an adjuvant with immunotherapeutic agents to improve the overall response of a patient's immune system to viral associated antigens.

*Advantages:* Enhanced T Cell Signaling should improve the overall effectiveness of immunotherapy producing a more robust patient response.

*Development Status:* Early stage, significant development efforts required to reach proof of principle.

*Inventors:* Lawrence E. Samelson *et al.* (NCI).

*Publication:* This work has not yet been published.

#### Patent Status

- U.S. Provisional Application No. 61/176,231 filed May 7, 2009 (HHS Reference No. E-159-2009/0-US-01).

- Interested parties wishing to review the U.S. Patent Application will need to sign a CDA.

*Related Technologies:* The NIH also has three patents related to the basic LAT molecule (HHS Reference No. E-010-1998)—US 7,118,889, AU 750543, and AU 776495—and several pending applications in the US published as 20060073562 A1 and 20070134749 A1 and corresponding applications in Canada (2316769) and Europe (1 141 281 A1).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Susan S. Rucker; 301-435-4478; [ruckersu@mail.nih.gov](mailto:ruckersu@mail.nih.gov).

#### Immunogenic Tumor-Associated Antigen SPANX-B for Selective Cancer Immunotherapy

*Description of Technology:*

Researchers at the National Institutes of

Health (NIH) have characterized a novel tumor-associated antigen, SPANX-B, that is naturally immunogenic and is expressed in a variety of human malignancies, including melanoma and lung, colon, renal, ovarian and breast carcinomas. In melanoma specifically, SPANX-B expression is associated with advanced and metastatic disease. Moreover, the researchers have found several agonist epitope peptides from SPANX-B which can be used to activate the immune system to eradicate tumors utilizing T cells. SPANX-B peptides have significant clinical and immunotherapeutic potential for the development of cancer diagnostic assays and potent protective and/or therapeutic vaccines to combat a wide-range of cancers.

#### Applications

- *In vitro* diagnostic assays for highly-metastatic melanomas or other cancers.
- Therapeutic monoclonal antibodies.
- Cancer vaccine development.

#### Advantages

- *Immunogenic:* SPANX-B peptides are naturally able to elicit immune response.

- Expressed in a wide-range of cancers.

- Use of epitope peptides facilitates the activation of cells of the more therapeutically effective branch of the immune system.

- *Small epitope peptides:* Can be more easily manufactured in contrast to recombinant proteins.

*Development Status:* Pre-clinical.

*Market:* Cancer; Cancer, Therapy; Cancer, Diagnostics/Prognostics.

*Inventors:* Arya Biragyn (NIA) and Vladimir Larionov (NCI).

*Publication:* G Almanzar *et al.* Sperm-derived SPANX-B is a clinically relevant tumor antigen that is expressed in human tumors and readily recognized by human CD4+ and CD8+ T cells. Clin Cancer Res. 2009 Mar 15;15(6):1954-1963.

*Patent Status:* U.S. Provisional Application No. 61/156,435 filed February 27, 2009 (HHS Reference No. E-089-2009/0-US-01).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Patrick P. McCue, Ph.D.; 301-435-5560; [mccuepat@mail.nih.gov](mailto:mccuepat@mail.nih.gov).

*Collaborative Research Opportunity:* The National Institute on Aging, Laboratory of Immunology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the use of SPANX-B-based therapeutic approaches to combat