

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****Proposed Collection; Comment Request; Alcohol Prevalence and Gene/Environment Interactions in Native American Tribes (a 10 Tribe Study)**

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

**Proposed Collection: Title:** Alcohol Prevalence and Gene/Environment Interactions in Native American Tribes (a 10 Tribe Study). **Type of Information Collection Request:** Extension. **Need and Use of Information Collection:** The Ten Tribe Study is being conducted to collect psychiatric and personal data from tribes with different rates of alcoholism. This data will be analyzed to determine, if possible, why tribes with similar lifestyles have different rates of alcoholism and alcohol abuse. Specifically, the information gathered during this study will be used to: (1) determine prevalence rates of alcoholism in 10 demographically sampled Native American tribes using structured or semi-structured interviews to rigorously diagnose alcoholism; (2) systematically diagnose conditions which are often comorbid with alcoholism including drug abuse, depression, and antisocial personality; (3) address crucial antecedents and consequences of alcoholism and environmental issues in alcohol vulnerability such as post-traumatic stress, violence, acculturation, and child abuse; and (4) investigate genetic vulnerability factors for tribal populations with high, moderate, and low alcoholism prevalence. This study has been ongoing for three years and is to be extended for three additional years. **Frequency of Response:** Once per respondent. **Affected Public:** Individuals. **Type of Respondents:** Adults. The annual reporting burden is as follows: *Estimated Number of*

*Respondents:* 1,800; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* 4.0; and *Estimated Total Annual Burden Hours Requested:* 7,200. There are no Costs to Respondents to report. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

**Request For Comments:** Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the extension of this collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) 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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Way to 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.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Ronni Nelson, Laboratory of Neurogenetics, Division of Intramural Clinical and Biological Research, NIAAA, NIH, 12420 Parklawn Drive, Suite 451, Rockville, Maryland 20852 or E-mail your request, including your address to: rn46h@nih.gov. Ms. Nelson can be contacted by telephone at 301-443-5781.

**COMMENTS DUE DATE:** Comments regarding this information collection are best assured of having their full effect if received on or before June 2, 2000.

Dated: March 28, 2000.

**Stephen Long,**

*Executive Officer, NIAAA.*

[FR Doc. 00-8103 Filed 3-31-00; 8:45 am]

**BILLING CODE 4140-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****National Heart, Lung, and Blood Institute Submission for OMB Review; Comment Request Women's Health Initiative Observation Study**

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Director, 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 of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on September 7, 1999, pages 48661-48662 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 current valid OMB control number.

**Proposed Collection: Title:** Women's Health Initiative (WHI) Observational Study. **Type of Information Collection Request:** REVISION: OBM No. 0925-0414, Expiration date: 06/30/2000. **Need and Use of Information Collection:** This study will be used by the NIH to evaluate risk factors for chronic disease among older women by developing and following a large cohort of postmenopausal women and relating subsequent disease development to baseline assessments of historical, physical, psychosocial, and physiologic characteristics. In addition, the observational study will complement the clinical trial (which has received clinical exemption) and provide additional information on the common causes of frailty, disability and death for postmenopausal women, namely, coronary heart disease, breast and colorectal cancer, and osteoporotic fractures. **Frequency of Response:** On occasion. **Affected Public:** Individuals and physicians. **Type of Respondents:** Women, next-of-kin, and physician's office staff. The annual reporting burden is as follows:

Type of respondents	Estimated number of respondents	Estimated number of responses per respondents	Average burden hours per response	Estimated total annual burden hours requested
OS Participants .....	82,044	.96876	.4557	36,219

Type of respondents	Estimated number of respondents	Estimated number of responses per respondents	Average burden hours per response	Estimated total annual burden hours requested
Next-of-kin .....	2,741	1	.0835	229
Physician's Office Staff .....	226	1	.0835	19
Total .....				36,467

The annualized cost burden to respondents is estimated at \$365,428. There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

**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 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 through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology permitting electronic submission of responses.

**DIRECT COMMENTS TO OMB:** Written comments and/or suggestions regarding 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 plan and instruments, contact: Dr. Linda Pottern, Project Officer, Women's Health Initiative Program Office, 6705 Rockledge Drive, 1 Rockledge Centre, Suite 300, MSC 7966, Bethesda, MD 20892-7966, or call (301) 402-2900 or E-Mail your request, including your address to: Linda\_Pottern@nih.gov

**COMMENTS DUE DATE:** Comments regarding this information collection are best assured of having their full effect if received on or before June 2, 2000.

Dated: March 20, 2000.

**Jacques E. Rossouw,**  
*Acting Director, Women's Health Initiative,*  
*NHLBI.*

[FR Doc. 00-8104 Filed 3-31-00; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Government-Owned Invention; Availability for Licensing: "Therapeutic Method to Treat Cancer and Define Cellular Regulatory Processes—Transcription Factor Decoy and Tumor Growth Factor"**

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

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S. Government and is 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.

**ADDRESSES:** Licensing information and a copy of the U.S. patent application referenced below may be obtained by contacting J. R. Dixon, Ph.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804 (telephone 301/496-7056 ext 206; fax 301/402-0220; E-Mail: jd212g@NIH.GOV). A signed Confidential Disclosure Agreement is required to receive a copy of any patent application.

**SUPPLEMENTARY INFORMATION:** *Invention Title:* "Transcription Factor Decoy and Tumor Growth Inhibitor".

*Inventors:* Dr. Yoon S. Cho-Chung (NCI).

*USPA SN:* 08/977,643 [= DHHS Ref. No. E-192-97/0]—Filed with the U.S.P.T.O. on November 24, 1997.

*Technology:* Alteration of gene transcription by inhibition of specific transcriptional regulatory proteins has important therapeutic potential. Synthetic double-stranded phosphorothioate oligonucleotides with high affinity for a target transcription factor can be introduced into cells as

decoy cis-elements to bind the factors and alter gene expression. The CRE (cyclic AMP response element)-transcription factor complex is a pleiotropic activator that participates in the induction of a wide variety of cellular and viral genes. Because the CRE cis-element, TGACGTCA, is palindromic, a synthetic single-stranded oligonucleotide composed of the CRE sequence self-hybridizes to form a duplex/hairpin. The CRE-palindromic oligonucleotide can penetrate into cells, compete with CRE enhancers for binding transcription factors, and specifically interfere with CRE- and AP-1-directed transcription *in vivo*. These oligonucleotides restrained tumor cell proliferation, without affecting the growth of noncancerous cells. This decoy oligonucleotide approach offers great promise as a tool for defining cellular regulatory processes and treating cancer and other diseases. [see J. Biol. Chem. 274, 1573-1580 (1999); online at <http://www.jbc.org/>]

The above mentioned Invention is available, including any available foreign intellectual property rights, for licensing.

Dated: March 24, 2000.

**Jack Spiegel,**

*Director, Division of Technology Development & Transfer, Office of Technology Transfer*

[FR Doc. 00-8106 Filed 3-31-00; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Opportunity for Licensing: Adenovirus Mediated Transfer of Genes**

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

**ACTION:** Notice.

**SUMMARY:** The National Institutes of Health (NIH), Public Health Service (PHS), Department of Health and Human Services (DHHS), seeks a licensee(s) to develop gene therapy-based therapeutics that would be effective in the treatment of a variety of disease states, particularly via transfer of specific genes to the lung. The inventors have developed adenoviral