

Dated: October 9, 2002.

Linda Arey Skladany,

Senior Associate Commissioner for External Relations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Electroencephalogram and Event-Related Potential Intermediate Phenotypes for Alcoholism in a Low Prevalence American Indian Tribe

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, regarding the 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 submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection Title: Electroencephalogram (EEG) and Event-Related Potential (ERP) intermediate phenotypes for alcoholism in a low prevalence American Indian tribe. Type of Information Collection Request: New. Need and Use of Information Collection: An extensive data set has already been collected by the Laboratory of Neurogenetics, NIAAA, on 294 members of a Southeastern American Indian tribe. We propose to re-contact these individuals to collect additional information. Approximately 100 of the original participants were originally selected as a representative sample of the population. The remaining 194 individuals are family members of alcoholic probands from the population sample. We propose to expand the study to collect (a) measures of intermediate phenotypes for alcoholism and (b) survey-based selected personality characteristics from the same tribal members. Intermediate phenotypes are biological traits that may be influenced by variation at fewer genes and may mediate different aspects of the disease. The intermediate phenotype measurements that we will collect include resting EEG phenotypes (low voltage alpha (LVA) and beta spectral power), ERPs and heart rate variability (HRV). LVA has been found to be more abundant in alcoholics with co-morbid anxiety disorders. Increased beta power has been associated with increased risk

of relapse. P300 ERP amplitude is reduced in alcoholics and their alcohol-naïve children. HRV is a potential intermediate phenotype for alcoholism and major depression. We also propose to administer the Temperament and Character Inventory, a standard, survey-based measure of harm avoidance, novelty seeking, reward dependence, and persistence. The use of such intermediate phenotypes and personality measures is likely to increase our ability to find vulnerability genes for alcoholism. We will use these EEG and EKG intermediate phenotypes and personality dimensions in (1) candidate gene analyses and (2) linkage analyses, utilizing the existing DNA, in order to determine the genes that increase an individual's risk for alcoholism and anxiety disorders.

The re-recruitment of the original study participants will start in spring 2003. The study is expected to run for 6 months. Frequency of response: Once per respondent. Affected Public: Individuals. Type of Respondents: Adult members of the Southeastern American Indian tribe who were participants in the original study.

The reporting burden is as follows: Estimated Number of Respondents: It is estimated, after a survey by tribal members, that we will be able to re-recruit approximately 280 of the 294 original participants. Estimated Number of Responses per Respondent: One response per respondent. Average Burden Hours per Response: Three hours per individual, for a total respondent burden of 840 hours. Estimated Total Annual Burden Hours Requested: 840 hours. 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 suggestions from the public and affected agencies are invited on the following points: (1) Whether the data collection 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; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways 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 Mary-Anne Enoch M.D., NIH/NIAAA/DICBR/LNG, 12420 Parklawn Drive, Park 5 Building, Room 451, MSC 8110, Bethesda, MD 20892-8110, or e-mail your request to: maenoch@niaaa.nih.gov. Dr. Enoch can be contacted by telephone at 301-496-2727.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: October 7, 2002.

Stephen Long,

Executive Officer, NIAAA.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Extended Lung Cancer Incidence Follow-Up for the Mayo Lung Project Participants

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), 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 August 5, 2002, page 50679-50680 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: Extended Lung Cancer Incidence Follow-Up for the Mayo Lung Project Participants. *Type of Information Collection Request:* EXTENSION, OMB No. 0925-0496, expiration date 10-31-2002. *Need and Use of Information Collection:* The Mayo Lung Project (MLP) was an NCI-funded randomized controlled trial (RCT) of lung cancer screening