

document. The draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 22, 2001.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 01-22287 Filed 9-5-01; 8:45 am]

BILLING CODE 4160-01-S

## 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 to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 30, 2001, page 21404, Volume 66, No. 83 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:** NEW. **Need and Use of Information Collection:** The Mayo Lung Project (MLP) was an NCI-funded randomized controlled trial (RCT) of lung cancer screening conducted among 9,211 male smokers from 1971 to 1983. No reduction in lung cancer mortality was observed in the MLP with an intense regimen of x-ray and sputum cytology screening. Recent analysis of update mortality and case survival data (through 1996) suggests that lesions with little-to-no clinical relevance (over-diagnosis) may have been detected through screening in the MLP intervention arm. Over-diagnosis leads to unnecessary medical interventions, including diagnostic and treatment procedures that carry with them varying

degrees of risk. Consequently, over-diagnosis can result in considerable harm, including premature death, which would not have occurred in the absence of screening. The persistence, after screening ends, of an excess of lung cancer cases in the intervention arm is the strongest evidence in support of over-diagnosis, but this information cannot be adequately obtained with available MLP data. Therefore, we propose to re-contact the MLP participants and/or their next-of-kin to determine the participants who were diagnosed with lung cancer after the formal end of the Project. These data will allow the NCI to either more-convincingly state or perhaps refute the possibility of over-diagnosis in lung cancer screening, and may be used to guide future research agendas and lung cancer screening policies. **Frequency of Response:** Once. **Affected public:** Individuals. **Type of Respondents:** MLP participants or their next-of-kin. The annual reporting burden is as follows: **Estimated Number of Respondents:** 6,223; **Estimated Number of Responses per Respondent:** 1. **Average Burden Hours Per Response:** 0.25; **Estimated Total Annual Burden Hours Requested:** 1,556. The annualized cost to respondents is estimated at \$27,230. 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 should address one or more of the following points: (1) 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) 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) 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.

**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. Pamela Marcus, Epidemiologist, Biometry Research Group, Division of Cancer Prevention, National Cancer Institute, Suite 344 EPN, 6130 Executive Blvd, Bethesda, MD 20892-7354; or call non-toll free 301-496-7468; or email [pm145q@nih.gov](mailto:pm145q@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: August 27, 2001.

**Reesa L. Nichols,**

*NCI Project Clearance Liaison.*

[FR Doc. 01-22352 Filed 9-5-01; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** Center for Scientific Review Special Emphasis Panel.

**Date:** September 4, 2001.

**Time:** 10 am to 12 pm.

**Agenda:** To review and evaluate grant applications.

**Place:** NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).

**Contact Person:** Gloria B. Levin, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, MSC 7848, Bethesda, MD 20892, (301) 435-1017, [leving@csr.nih.gov](mailto:leving@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

**Name of Committee:** Center for Scientific Review Special Emphasis Panel.

**Date:** September 5, 2001.

*Time:* 1 pm to 2 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Anne E Schaffner, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7850, Bethesda, MD 20892, (301) 435-1239, [schaffna@csr.nih.gov](mailto:schaffna@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel.

*Date:* September 9-11, 2001.

*Time:* 6 pm to 9 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Hotel St. Francis, 219 Don Gasper Avenue, Sante Fe, NM 87501.

*Contact Person:* Eugene Vigil, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5144, MSC 7840, Bethesda, MD 20892, (301) 435-1025.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel.

*Date:* September 13, 2001.

*Time:* 2 pm to 3 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* H. Mac Stiles, PhD, MPH, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3170, MSC 7770, Bethesda, MD 20892, (301) 435-1785.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 28, 2001.

**Anna Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 01-22351 Filed 9-5-01; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Loan Repayment Program for Clinical Researchers

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** Pending approval by the Office of Management and Budget (OMB) under the requirements of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) announces the availability of educational loan repayment under the NIH Loan Repayment Program for Clinical Researchers (the Program). The Program, which is authorized by section 487F of the Public Health Service (PHS) Act (42 U.S.C. 288-5a), as added by the Public Health Improvement Act of 2000 (Pub. L. 106-505), provides for the repayment of the educational loan debt of qualified health professionals who agree to conduct clinical research. The Program provides for the repayment of up to \$35,000 of the principal and interest of the educational loans of such health professionals for each year of obligated service. The purpose of the Program is the recruitment and retention of highly qualified health professionals as clinical investigators. Through this notice, the NIH invites qualified health professionals who contractually agree to engage in clinical research for at least two years, to apply for participation in the NIH Loan Repayment Program for Clinical Researchers.

**DATES:** Interested persons may request information about the Program beginning on September 6, 2001.

**ADDRESSES:** Information regarding the requirements and application procedures for the Program may be obtained by calling or writing: Marc S. Horowitz, J.D., Office of Loan Repayment and Scholarship, National Institutes of Health, 2 Center Drive, Room 2E30, Bethesda, MD 20892-0230 or call non-toll-free number (301) 402-5666 or e-mail your request, including your address, to [lrp@nih.gov](mailto:lrp@nih.gov).

**SUPPLEMENTARY INFORMATION:** The Public Health Improvement Act of 2000 (Pub. L. 106-505) was enacted on November 13, 2000 adding section 487F of the Public Health Service (PHS) Act (42 U.S.C. 288-5a). Section 487F authorizes the Secretary, acting through the Director of the NIH, to carry out a program of entering into contracts with appropriately qualified health professionals. Under such contracts, qualified health professionals agree to conduct clinical research for at least two years in consideration of the Federal Government agreeing to repay, for each year of service, not more than \$35,000 of the principal and interest of the educational loans of such health professionals. This program is known as

the NIH Loan Repayment Program for Clinical Researchers (LRP-CR).

#### Eligibility Criteria

Specific eligibility criteria with regard to participation in the LRP for Clinical Researchers include the following:

(1) Participants must be United States citizens, nationals, or permanent residents;

(2) Participants must have a M.D., Ph.D., Pharm.D., D.O., D.D.S., D.M.D., D.P.M., D.C., N.D., or equivalent degree;

(3) Participants must be affiliated with the NIH in one of the following ways:

(a) a recipient of postdoctoral National Research Service Award support on an individual postdoctoral fellowship (F32) or an institutional research training grant (T32). NRSA recipients will only be eligible for loan repayment during the first and third year of NRSA support. The second year of postdoctoral NRSA involves repayment of a service obligation incurred during the first year of NRSA support which eliminates the possibility of concurrent participation in the loan repayment program.

(b) a recipient of support under an individual or institutional research career development award including the following mechanisms:

(1) K01, the Mentored Research Scientist Development Award,

(2) K07, the Academic Clinical Scientist Development Award,

(3) K08, the Mentored Clinical Scientist Development Award,

(4) K12, Mentored Clinical Scientist Development Program Award,

(5) K22, the Career Transition Award with an extramural phase,

(6) K23, the Mentored Patient-Oriented Research Career Development Award, or

(7) K25, the Mentored Quantitative Research Career Development Award.

(c) a first-time recipient of NIH grant support as the principal investigator of an

(1) R01, a research project grant consisting of one research project,

(2) R03, a small research grant,

(3) R21, an exploratory/developmental grant,

(4) U01, a cooperative agreement consisting of one research project.

(d) a first-time director of subprojects on multicomponent center grants (P series grants, program project grants (P01)), or multicomponent cooperative agreements (U series).

(4) Participants must have qualifying educational debt in excess of 20 percent of their annual income or compensation, as applicable, at their expected date of program eligibility. The expected date of program eligibility is the date by which