

among racial/ethnic minority populations. NCI will sponsor questions on cancer screening in the 2003 NHIS and to provide better estimates for smaller racial-ethnic minority populations, anticipates also sponsoring

cancer screening questions on the 2003 CHIS. NCI will also take advantage of the Housing and Environment Module to be included in the 2003 CHIS to ask respondents questions about

environmental tobacco smoke and physical activity.

*Frequency of response:* One-time. *Affected public:* Individuals. *Types of Respondents:* U.S. adults. The annual reporting burden is as follows:

A.12-1 ESTIMATES OF HOUR BURDEN—2003 CHIS CANCER CONTROL MODULE

Type of respondent	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Adult Individuals—Pilot .....	150	1	.09	13.50
Adult Individuals—Survey .....	55,000	1	.09	4,950.00
<b>Total Annual Hour Burden .....</b>				<b>4,963.50</b>

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 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 20530, 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 Nancy Breen, Ph.D., Project Officer, National Cancer Institute, EPN 4005, 6130 Executive Boulevard MSC 7344, Bethesda, Maryland 20892-7344, or call non-toll-free number (301) 496-8500, or FAX your request to (301) 435-3710, or E-mail your request, including your address, to [breenn@mail.nih.gov](mailto:breenn@mail.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: March 28, 2003.

**Reesa L. Nichols,**

*NCI Project Clearance Liaison.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institutes of Health Extramural Loan Repayment Program for Clinical Researchers**

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

**ACTION:** Notice.

**SUMMARY:** The National Institutes of Health (NIH) announces the availability of educational loan repayment under the NIH Extramural Loan Repayment Program for Clinical Researchers (LRP-CR). The Loan Repayment Program for Clinical Researchers, which is authorized by section 487F<sup>1</sup> of the Public Health Service (PHS) Act (42 U.S.C. 288-5a), as added by the Clinical Research Enhancement Act of the Public Health Improvement Act of 2000 (Public Law 106-505), provides for the repayment of the existing educational loan debt of qualified health professionals who agree to conduct clinical research. The Loan Repayment Program for Clinical Researchers provides for the repayment of up to \$35,000 of the principal and interest of the extant educational loans of such health professionals for each year of obligated service. Payments equal to 39

<sup>1</sup> So in the law. There are two sections 487F. Section 205 of Public Law 106-505 (114 Stat. 2329), inserted section 487F after section 487E. Previously, section 1002(b) of Public Law 106-310 (114 Stat. 1129), which relates to a Pediatric Research Loan Repayment Program, inserted section 487F after section 487E.

percent of total loan repayments are issued to the Internal Revenue Service on behalf of program participants to offset Federal tax liabilities incurred. The purpose of the Loan Repayment Program for Clinical Researchers 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, and who agree to engage in such research for at least 50 percent of their time, *i.e.*, not less than 20 hours per week, to apply for participation in the NIH Loan Repayment Program for Clinical Researchers.

**DATE:** Interested persons may request information about the Loan Repayment Program for Clinical Researchers on April 8, 2003.

**FOR FURTHER INFORMATION CONTACT:** Jerry Moore, NIH Regulations Officer, Office of Management Assessment, NIH, 6011 Executive Blvd., Room 601, MSC 7669, Rockville, MD 20892, by email ([jm40z@nih.gov](mailto:jm40z@nih.gov)), by fax 301-402-0169, or by telephone 301-496-4607 (not a toll-free number). For program information contact Marc S. Horowitz, email [lrp@nih.gov](mailto:lrp@nih.gov), or telephone 301-402-5666 (not a toll free number). Information regarding the requirements, application deadline dates, and an on-line application for the Clinical Research Loan Repayment Program may be obtained at the NIH Loan Repayment Program Web site, <http://www.lrp.nih.gov>.

**SUPPLEMENTARY INFORMATION:** The Clinical Research Enhancement Act, which is contained in the Public Health Improvement Act of 2000 (Pub. L. 106-505), was enacted on November 13, 2000, adding section 487F of the 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 research service, not more than \$35,000 of the principal and interest of the extant qualified educational loans of such health professionals. Payments equal to 39 percent of total loan repayments are issued to the Internal Revenue Service on behalf of program participants to offset Federal tax liabilities incurred. 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 Loan Repayment Program for Clinical Researchers include the following:

1. Applicants must be U.S. citizens, U.S. nationals, or permanent residents of the United States;
2. Applicants must have a Ph.D., M.D., D.O., D.D.S., D.M.D., D.P.M., Pharm.D., D.C., N.D., or equivalent doctoral degree from an accredited institution;
3. Applicants must have total qualifying educational loan debt equal to or in excess of 20 percent of their institutional base salary on the date of program eligibility (the effective date that a loan repayment contract has been executed by the Secretary of Health and Human Services or designee), expected to be between June 1 and August 1, 2003. Institutional base salary is the annual amount that the organization pays for the participant's appointment, whether the time is spent in research, teaching, patient care, or other activities. Institutional base salary excludes any income that a participant may earn outside the duties of the organization. Institutional base salary may not include or comprise any income (salary or wages) earned as a Federal employee;
4. Applicants must conduct qualifying research supported by a non-profit foundation, non-profit professional association, or other non-profit institution, or a U.S. or other government agency (Federal, State, or local). A foundation, professional association, or institution is considered to be non-profit if exempt from Federal tax under the provisions of section 501 of the Internal Revenue Code (26 U.S.C. 501);
5. Applicants must engage in qualified clinical research. Clinical research is defined as patient-oriented clinical research conducted with human

subjects or research on the causes and consequences of disease in human populations involving material of human origin (such as tissue specimens and cognitive phenomena) for which an investigator or colleague directly interacts with human subjects in an outpatient or inpatient setting to clarify a problem in human physiology, pathophysiology or disease, or epidemiologic or behavioral studies, outcomes research or health services research, or developing new technologies, therapeutic interventions, or clinical trials;

6. Applicants must engage in qualified clinical research for at least 50 percent of their time, *i.e.*, not less than 20 hours per week;

7. Full-time employees of Federal government agencies are ineligible to apply for LRP benefits. Part-time Federal employees who engage in qualifying research as part of their non-Federal duties for at least 20 hours per week, and whose funding source is from a non-profit source as defined in number 4 of this section, are eligible to apply for loan repayment if they meet all other eligibility requirements;

8. Applicants must agree to conduct research for which funding is not prohibited by Federal law, regulation, or HHS/NIH policy. Recipients who receive LRP awards must conduct their research in accordance with applicable Federal, State and local law (*e.g.*, applicable human subject protection regulations);

9. Applicants will not be excluded from consideration under the Loan Repayment Program for Clinical Researchers on the basis of age, race, culture, religion, gender, sexual orientation, disability, or other non-merit factors; and

10. No individual may submit more than one LRP application to the NIH in any fiscal year. Individuals who have applied previously for the LRP-CR but did not receive an award are eligible to submit a new application if they meet all of the above eligibility criteria.

The following individuals are ineligible for participation in the Loan Repayment Program for Clinical Researchers:

1. Persons who are not United States citizens, nationals, or permanent residents;

2. Any individual who has a Federal judgment lien against his/her property arising from a Federal debt is barred from receiving Federal funds until the judgment is paid in full or satisfied;

3. Any individual who owes an obligation of health professional service to the Federal government, a State, or other entity, unless deferrals or

extensions are granted for the length of their Extramural Loan Repayment Program service obligation. The following are examples of programs with service obligations that disqualify an applicant from consideration, unless a deferral for the length of participation in the Loan Repayment Program for Clinical Researchers is obtained:

- Armed Forces (Army, Navy, or Air Force) Professions Scholarship Program,
- Exceptional Financial Need (EFN) Scholarship Program,
- Financial Assistance for Disadvantaged Health Professions Students (FADHPS),
- Indian Health Service (IHS) Scholarship Program,
- National Health Service Corps (NHSC) Scholarship Program,
- National Institutes of Health Undergraduate Scholarship Program (UGSP),
- Physicians Shortage Area Scholarship Program,
- Primary Care Loan (PCL) Program,
- Public Health Service (PHS) Scholarship Program, and
- National Research Service Award (NRSA) Program—a recipient of postdoctoral National Research Service Award support from an individual postdoctoral fellowship (F32) or an institutional research training grant (T32) is eligible for loan repayment. NRSA recipients incur a service obligation of 12 months for their first year of NRSA support. This obligation is usually repaid in the second year of the NRSA award.

**Note:** NRSA service and loan repayment service obligations cannot be concurrently satisfied. There are two options for NRSA LRP recipients: (1) Defer receipt of LRP payments in the 2nd year of NRSA support to fulfill their obligation; or (2) request an extension of time to fulfill the NRSA service obligation in order to satisfy the LRP service obligation while also receiving loan repayment.

4. Full-time employees of Federal government agencies;

5. Current recipients of NIH Intramural Research Training Awards (IRTA) or Cancer Research Training Awards (CRTA);

6. Individuals conducting research for which funding is precluded by Federal law, regulations or HHS/NIH policy, or that does not comply with applicable Federal, State, and local law regarding the conduct of the research (*e.g.*, applicable human subject protection regulations); and

7. Individuals with ineligible loans, which include loans that have been consolidated with a loan of another individual (including spouses or

children), or loans that are not educational, such as home equity loans.

### Selection Process

Upon receipt, applications for the Loan Repayment Program for Clinical Researchers will be reviewed for eligibility and completeness by the NIH Office of Loan Repayment. Incomplete or ineligible applications will not be processed for review. Applications that are complete and eligible will be referred to the appropriate NIH Institute or Center for peer review by the NIH Center for Scientific Review (CSR). In evaluating the application, reviewers will be directed to consider the following components as they relate to the likelihood that the applicant will continue in a clinical research career:

- a. Potential of the applicant to pursue a career in clinical research.

- Appropriateness of the applicant's previous training and experience to prepare him/her for a clinical research career.

- Suitability of the applicant's proposed clinical research activities in the two-year loan repayment period to foster a research career.

- Assessment of the applicant's commitment to a research career as reflected by the personal statement of long-term career goals and the plan outlined to achieve those goals.

- Strength of recommendations attesting to the applicant's potential for a research career.

- b. Quality of the overall environment to prepare the applicant for a clinical research career.

- Availability of appropriate scientific colleagues to achieve and/or enhance the applicant's research independence.

- Quality and appropriateness of institutional resources and facilities.

The following information is furnished by the applicant or others on behalf of the applicant (forms are completed electronically at the NIH LRP Web site, [www.lrp.nih.gov](http://www.lrp.nih.gov)):

Applicants electronically transmit the following to the NIH Office of Loan Repayment:

1. Applicant Information Statement.
2. Biosketch.
3. Personal Statement, which includes a discussion of career goals and academic objectives.
4. Description of Research Activities, which describes the current or proposed research project including the specific responsibilities and role of the applicant in conducting the research. The research supervisor or mentor will be asked to concur in the research project description provided by the applicant.
5. Identification of three Recommenders (one of whom is

identified as research supervisor or mentor).

6. Identification of Institutional Contact.

7. On-line Certification.

8. Current account statement(s), and promissory note(s) or disclosure statement(s), obtained from lending institution(s), submitted via facsimile to 866-849-4046.

9. If applying based on NIH support, Notice of Grant/Award (or PHS Form Number 2271 for T32 recipients).

Research supervisors or mentors electronically transmit the following to the NIH Office of Loan Repayment:

1. Recommendation.

2. Biosketch.

3. Assessment of the Research Activities Statement submitted by the applicant.

4. Description of the Research Environment, which provides detailed information about the lab where the applicant is or will be conducting research, including funding, lab space, and major areas under investigation.

5. Training or Mentoring Plan, which includes a detailed discussion of the training or mentoring plan, including a discussion of the research methods and scientific techniques to be taught. This document is completed by the research supervisor or mentor and is submitted for all applicants (except for applicants with an NIH R01 or equivalent grant).

6. Biosketch of a laboratory staff member if involved in training or mentoring the applicant.

The other two Recommenders electronically transmit recommendations to the NIH Office of Loan Repayment.

Institutional Contacts electronically transmit the following to the NIH Office of Loan Repayment:

A certification that: (a) Assures the applicant will be provided the necessary time and resources to engage in the research project for two years from the date a Loan Repayment Program Contract is executed; (b) assures that the applicant is or will be engaged in qualifying research for 50 percent of his/her time, *i.e.*, not less than 20 hours per week; (c) certifies that the institution is non-profit (exempt from tax under 26 U.S.C. 501) or is a U.S. or other government agency (Federal, State, local); and (d) provides the applicant's institutional base salary.

### Program Administration and Details

Under the Loan Repayment Program for Clinical Researchers, the NIH will repay a portion of the extant qualified educational loan debt incurred to pay for the researcher's undergraduate, graduate, and/or health professional

school educational expenses.

Individuals must have total qualified educational debt that equals or exceeds 20 percent of their institutional base salary on the date of program eligibility. This is called the debt threshold. The formula used to calculate the potential annual loan repayment amount is total educational debt less the participant obligation (an amount equal to 10 percent of institutional base salary), which yields the total repayable debt; the total repayable debt is divided by 25 percent, which yields the potential annual repayment amount (up to \$35,000). Participants are encouraged to pay the participant obligation during the contract period.

Following is an example of loan repayment calculations: an applicant has a loan debt of \$100,000 and a university compensation of \$40,000. Since the loan debt exceeds the debt threshold (20 percent of university compensation = \$8,000), the applicant has sufficient debt for loan repayment consideration. The participant obligation is 10 percent of the institutional base salary, in this case \$4,000. Thus, repayment of the \$4,000 debt is the applicant's responsibility. The remaining amount, in this example \$96,000 (total repayable debt) will be considered for repayment on a graduated basis. In this case, the maximum to be repaid in the initial two-year contract is \$48,000 or \$24,000 per year, plus tax reimbursement benefits.

The total repayable debt will be paid at the rate of one-quarter per year, subject to a statutory limit of \$35,000 per year, for each year of obligated service. Individuals are required to initially engage in 2 years of qualified clinical research.

Following conclusion of the initial two-year contract, participants may competitively apply for renewal contracts if they continue to engage in qualified clinical research. These continuation contracts may be approved on a year-to-year basis, subject to a finding by NIH that the applicant's clinical research accomplishments are acceptable, qualified clinical research continues, and non-profit institutional or U.S. or other government agency (Federal, State, or local) support has been assured. Renewal applications are competitively reviewed and the submission of a renewal application does not assure the award of benefits. Funding of renewal contracts is also contingent upon an appropriation and/or allocation of funds from the U.S. Congress and/or the NIH or the NIH Institutes and Centers.

In return for the repayment of their educational loans, participants must agree to (1) engage in qualified clinical research for a minimum period of two years; (2) engage in such research for at least 50 percent of their time, *i.e.*, not less than 20 hours per week; (3) make payments to lenders on their own behalf for periods of Leave Without Pay (LWOP); (4) pay monetary damages as required for breach of contract; and (5) satisfy other terms and conditions of the LRP contract. Applicants must submit a signed contract, prepared by the NIH, agreeing to engage in qualified clinical research at the time they submit an application. Substantial monetary penalties will be imposed for breach of contract.

The NIH will repay lenders for the extant principal, interest, and related expenses (such as the required insurance premiums on the unpaid balances of some loans) of qualified U.S. or other government (Federal, State, local), academic institutions, and commercial or other chartered U.S. lending institution educational loans obtained by participants for the following:

- (1) Undergraduate, graduate, and health professional school tuition expenses;
- (2) Other reasonable educational expenses required by the school(s) attended, including fees, books, supplies, educational equipment and materials, and laboratory expenses; and
- (3) Reasonable living expenses, including the cost of room and board, transportation and commuting costs, and other living expenses as determined by the Secretary.

Repayments are made directly to lenders, following receipt of (1) the Principal Investigator, Program Director, or Research Supervisor's verification of completion of the prior period of research, and (2) lender verification of the crediting of prior loan repayments, including the resulting account balances and current account status. The NIH will repay loans in the following order, unless the Secretary determines that significant savings would result from a different order of priority:

- (1) Loans guaranteed by the U.S. Department of Health and Human Services:
  - Health Education Assistance Loan (HEAL);
  - Health Professions Student Loan (HPSL);
  - Loans for Disadvantaged Students (LDS); and
  - Nursing Student Loan Program (NSL);
- (2) Loans guaranteed by the U.S. Department of Education:

- Direct Subsidized Stafford Loan;
- Direct Unsubsidized Stafford Loan;
- Direct Consolidation Loan;
- Perkins Loan;
- FFEL Subsidized Stafford Loan;
- FFEL Unsubsidized Stafford Loan;

and

- FFEL Consolidation Loan;
- (3) Loans made or guaranteed by a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or possession of the United States;

(4) Loans made by academic institutions; and

(5) Private ("Alternative")

Educational Loans:

- MEDLOANS; and
- Private (non-guaranteed) Consolidation Loans.

The following loans are NOT repayable under the Loan Repayment Program for Clinical Researchers:

(1) Loans not obtained from a U.S. or other government entity, academic institution, or a commercial or other chartered U.S. lending institution such as loans from friends, relatives, or other individuals, and non-educational loans, such as home equity loans;

(2) Loans for which contemporaneous documentation (current account statement, and promissory note or lender disclosure statement) is not available;

(3) Loans that have been consolidated with loans of other individuals, such as a spouse or child;

(4) Loans or portions of loans obtained for educational or living expenses, which exceed a reasonable level, as determined by the standard school budget for the year in which the loan was made, and are not determined by the LRP to be reasonable based on additional contemporaneous documentation provided by the applicant;

(5) Loans, financial debts, or service obligations incurred under the following programs, or other programs that incur a service obligation that converts to a loan on failure to satisfy the service obligation:

- Armed Forces (Army, Navy, or Air Force) Health Professions Scholarship Program;
  - Indian Health Service (IHS) Scholarship Program;
  - National Institutes of Health Undergraduate Scholarship Program (UGSP);
  - National Research Service Award (NRSA) Program;
  - Physicians Shortage Area Scholarship Program (Federal or State);
  - Primary Care Loan (PCL) Program;
- and

- Public Health Service (PHS) and National Health Service Corps (NHSC) Scholarship Program;

(6) Delinquent loans, loans in default, or loans not current in their payment schedule;

(7) PLUS Loans;

(8) Loans that have been paid in full; and

(9) Loans obtained after the execution of the NIH Loan Repayment Program Contract (*e.g.*, promissory note signed after the LRP contract has been awarded).

Before the commencement of loan repayment, or during lapses in loan repayments, due to NIH administrative complications, Leave Without Pay (LWOP), or a break in service, LRP participants are wholly responsible for making payments or other arrangements that maintain loans current, such that increases in either principal or interest do not occur. The LRP contract period will not be modified or extended as a result of Leave Without Pay (LWOP) or a break in service. Penalties assessed participants as a result of NIH administrative complications to maintain a current payment status may not be considered for reimbursement.

LRP payments are NOT retroactive. Loan repayment for Fiscal Year 2003 will commence after a loan repayment contract has been executed, which is expected to be no earlier than June 2003.

#### Additional Program Information

This program is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs.

This program is subject to OMB clearance under the requirements of the Paperwork Reduction Act of 1995. The OMB approval of the information collection associated with the Loan Repayment Program for Clinical Researchers expires on December 31, 2004. The Catalog of Federal Domestic Assistance number for the Loan Repayment Program for Clinical Researchers is 93.280.

Dated: January 24, 2003.

**Elias A. Zerhouni,**

*Director, NIH.*

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