

## EXTRAMURAL LOAN REPAYMENT PROGRAM FOR CLINICAL RESEARCHERS

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NOTICE: NOT-OD-04-060

National Institutes of Health (NIH)

APPLICATION PERIOD: September 1, 2004, through 5 PM EST, December 15, 2004

### THIS NOTICE ADDRESSES THE FOLLOWING TOPICS:

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### PURPOSE OF THIS NOTICE

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 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 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.

LRP-CR applications will be accepted September 1 through December 15, 2004. They must be submitted via the NIH Loan Repayment Website, <http://www.lrp.nih.gov>.

### WHERE TO OBTAIN ADDITIONAL INFORMATION

For questions on the LRP-CR program, please see the LRP website at <http://www.lrp.nih.gov>, send an email to [lrp@nih.gov](mailto:lrp@nih.gov), or call the LRP helpline at (866) 849-4047.

Direct your remaining questions regarding your research project to the relevant NIH scientific program contact listed on the LRP website at <http://www.lrp.nih.gov/contact/index.htm>.

## PROGRAM OBJECTIVES

The objective of the program is to recruit and retain highly qualified health professionals as clinical investigators.

NIH defines clinical research 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 epidemiological or behavioral studies, outcomes research or health services research, or developing new technologies, therapeutic interventions, or clinical trials.”

## FUNDS AVAILABLE

The NIH intends to commit \$43 million in Fiscal Year 2005 to fund approximately 750 LRP-CR individuals.

## AWARD CRITERIA

Applications for the LRP-CR are evaluated against 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.
  - o Appropriateness of the applicant’s previous training and experience to prepare him/her for a clinical research career.
  - o Suitability of the applicant’s proposed clinical research activities in the two-year loan repayment period to foster a research career.
  - o 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.
  - o 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.
  - o Availability of appropriate scientific colleagues to achieve and/or enhance the applicant’s research independence.

- o Quality and appropriateness of institutional resources and facilities.

Renewal applications are competitive and are evaluated using the same criteria as new applications plus two additional criteria - an assessment of research accomplishments and development of an individual as an independent investigator.

## ELIGIBLE APPLICANTS

Specific eligibility criteria with regard to participation in the Loan Repayment Program for Clinical Researchers include the following:

1. Applicants must be a U.S. citizen, U.S. national, or permanent resident of the United States;
2. Applicants must have a M.D., Ph.D., Pharm. D., Psy.D., D.O., D.D.S., D.M.D., D.P.M., 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 July 1 and September 1, 2005. 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 domestic 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 domestic 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 based on a 40 hour 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 domestic 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;

4. Full-time employees of Federal Government agencies. Part-time Federal employees who engage in qualifying research supported by a domestic non-profit institution, as part of their non-Federal duties, for an outside entity for at least 20 hours per week, based on a 40 hour week, are eligible to apply for the LRP-CR if they meet all other eligibility requirements;
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.

#### RECEIPT, PEER REVIEW, AND REVIEW SCHEDULE

Upon receipt, applications for both initial and renewal awards will be reviewed for eligibility and completeness by the NIH Loan Repayment Program. Incomplete or ineligible applications will not be considered. Applications that are complete and eligible will be forwarded to the NIH Center for Scientific Review (CSR), which will assign the application to an NIH Institute or Center for peer review.

Application Receipt Date: December 15, 2004, 5 P.M. EST

Peer Review Date: March-May, 2005

Anticipated Award Date: June-August, 2005

#### APPLICATION MATERIALS (New and Renewal Applicants)

The following information is furnished by applicants or others on behalf of applicants (forms are completed electronically at the NIH LRP Web-site, <http://www.lrp.nih.gov>), and must be submitted from September 1, 2004, through December 15, 2004 at 5 PM EST:

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.

5. Identification of three recommenders (including research supervisor or mentor).
6. Identification of institutional contact.
7. On-line certification.
8. Loan information, including 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 2271 for Ruth L. Kirschstein NRSA training fellowships).

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.

Recommenders electronically transmit recommendation forms to the NIH Office of Loan Repayment.

Institutional contacts electronically transmit a certification to the NIH Office of Loan Repayment 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 the applicant is or will be engaged in qualifying research for 50 percent of their work effort or not less than 20 hours per week based upon a 40 hour week;
- (c) certifies the sponsoring entity is a domestic non-profit institution (exempt from tax under 26 USC 501); and
- (d) identifies the applicant's institutional base salary.

## RENEWAL APPLICATIONS

Recipients who wish to extend their NIH loan repayment should reapply during the 2005 application cycle if their initial LRP contract began in 2003.

LRP renewal contracts are available for one- and two-year periods and are based upon the same criteria as the initial application plus two additional criteria - an assessment of

research accomplishments and development of an individual as an independent investigator. An explanation of research accomplishments during the initial award period is required. Progress toward development as an independent investigator is a major factor in awarding renewal of loan repayment support. Renewal LRP awards are competitive and submission of a renewal application does not assure the award of loan repayment.

## 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.

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 educational loans from a U.S. government entity, academic institution, or a commercial or other chartered U.S. lending institution, such as banks, credit unions, savings and loan associations, not-for-profit organizations, insurance companies, and other financial or credit institutions which are subject to examination and supervision in their capacity as lending institutions by an agency of the United States or of the State in which the lender has its principal place of business, 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:

- o Health Education Assistance Loan (HEAL);
- o Health Professions Student Loan (HPSL);
- o Loans for Disadvantaged Students (LDS); and
- o Nursing Student Loan Program (NSL);

(2) Loans guaranteed by the U.S. Department of Education:

- o Direct Subsidized Stafford Loan;
- o Direct Unsubsidized Stafford Loan;
- o Direct Consolidation Loan;
- o Perkins Loan;
- o FFEL Subsidized Stafford Loan;
- o FFEL Unsubsidized Stafford Loan; and
- o 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:

- o MEDLOANS; and
- o 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:
  - o Armed Forces (Army, Navy, or Air Force) Health Professions Scholarship Program;
  - o Indian Health Service (IHS) Scholarship Program;
  - o National Institutes of Health Undergraduate Scholarship Program (UGSP);
  - o National Research Service Award (NRSA) Program;
  - o Physicians Shortage Area Scholarship Program (Federal or State);
  - o Primary Care Loan (PCL) Program; and
  - o 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) (this provision does not apply to qualifying loan consolidations).

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 2005 will commence after a loan repayment contract has been executed, which is expected

to be no earlier than July 2005.

#### CITATIONS OF FEDERAL AUTHORITY

Awards are made pursuant to the Public Health Improvement Act of November 2000 (Public Law 106-505), also known as the Clinical Research Enhancement Act, which added Section 487F of the Public Health Service (PHS) Act (42 U.S.C. 288-5a) [So in 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.] The Federal Debt Collection Procedures Act of 1990, contained in Public Law 101-647, requires that an individual that has a judgment lien against his/her property for a debt to the United States shall not be eligible to receive funds directly from the Federal government in any program, except funds to which the debtor is entitled as a beneficiary, until the judgment is paid in full or otherwise satisfied (28 USC 3201). The Catalog of Federal Domestic Assistance number for the LRP for Clinical Researchers is 93.280.

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