

expires on October 31, 2007. The guidance document also refers to labeling requirements, annual reporting requirements, and other information collections established under existing regulations. The collections of information described in section III of the guidance that result from § 809.10 were approved under OMB control number 0910-0485. The collections of information described in section III of the guidance that result from §§ 610.60, 610.61, and 610.62 were approved under OMB control number 0910-0338. The collections of information described in section III of the guidance that result from part 660 (§§ 660.2, 660.28, 660.35, 660.45, and 660.55) were approved under OMB control number 0910-0527. The collections of information described in section X of the guidance, regarding annual reports, were approved under OMB control numbers 0910-0231 and 0910-0338. The collections of information described in section X of this guidance, regarding adverse event reporting, were approved under OMB control numbers 0910-0437 and 0910-0291.

V. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 9, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04-26333 Filed 11-29-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Health Extramural Clinical Research Loan Repayment Program for Individuals From Disadvantaged Backgrounds

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) and the National Center on

Minority Health and Health Disparities (NCMHD) announce the 2005 Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (ECR-LRP or Program). The ECR-LRP provides for the repayment of educational loan debt of up to \$35,000 annually for qualified health professionals from disadvantaged backgrounds conducting clinical research for domestic non-profit or government entities. In addition, the program will cover up to 39 percent of the Federal tax liability resulting from loan repayments, and may provide reimbursement for State and local tax liabilities.

The purpose of the Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds is the recruitment and retention of highly qualified health professionals from disadvantaged backgrounds in careers in clinical research. Through this notice, the NIH and NCMHD invite qualified health professionals who are from disadvantaged backgrounds and interested in engaging in clinical research for at least two years, and who agree to engage in this area of research for at least 50 percent of their time, *i.e.*, no less than 20 hours per week, to apply for participation in the NIH Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (ECR-LRP).

DATES: Interested persons may request information about the Program beginning on November 30, 2004.

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 e-mail: Moorej@mail.nih.gov, by fax: 301-402-0169, or by telephone: 301-496-4607 (not a toll-free number). For information regarding the requirements, application deadline dates, and on-line application for the ECR-LRP program, please visit the NIH Loan Repayment Program Web site at <http://www.lrp.nih.gov>, send an e-mail to lrp@nih.gov, call the LRP helpline at 866-849-4047 (toll-free number) or contact the NCMHD Loan Repayment Coordinator, Kenya McRae, at 301-402-1366 (not a toll-free number) or via e-mail: mcraek@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds, which was originally authorized by section 487E of the Public Health Service (PHS) Act (42 U.S.C. 288-5), as

amended by the National Institutes of Health Revitalization Act of 1993 (Pub. L. 103-43), provides for the repayment of the educational loan debt of health professionals who are from disadvantaged backgrounds, who have substantial debt relative to income, and who agree to conduct clinical research as employees of the NIH. The Consolidated Appropriations Act of 2001 (Pub. L. 106-554) amended section 487E of the PHS Act to allow expansion of the existing program to include health professionals who are not employees of the National Institutes of Health. Under the expanded authority, the Secretary of Health and Human Services (HHS) in consultation with the Director of NIH will enter into contracts with qualified health professionals from disadvantaged backgrounds under which such health professionals agree to conduct clinical research; in return, the Federal Government agrees to repay for each year of such research, up to \$35,000 of their student loan debt.

The objective of the ECR-LRP is the recruitment and retention of highly qualified health professionals from disadvantaged backgrounds to clinical research careers. The emphasis on clinical research and individuals from disadvantaged backgrounds highlights the need for the involvement of a cadre of competent health professionals in clinical research.

“Clinical research” as defined in section 206 of Pub. L. 106-505, the Public Health Improvement Act, enacted on November 13, 2000, means 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.

“An individual from a disadvantaged background” is defined as one who comes from a family with an annual income below a level based on low-income thresholds according to family size published by the U.S. Bureau of the Census, adjusted annually for the changes in the Consumer Price Index, and adjusted by the Secretary of the U.S. Department of Health and Human Services (Secretary) for use in all health professions programs. The Secretary

periodically publishes these income levels in the **Federal Register**. An applicant must certify his or her disadvantaged status under the above definition by submitting (a) a written statement from the individual's former health professions school(s) that indicates that he or she qualified for Federal disadvantaged assistance during attendance; or (b) documentation that he or she received any financial aid from Health Professions Student Loans (HPSL) or Loans for Disadvantaged Student Program; or (c) documentation that he or she received scholarships from the U.S. Department of Health and Human Services (HHS) under the Scholarship for Individuals with Exceptional Financial Need.

Eligibility Criteria

Specific eligibility criteria for the ECR-LRP include the following:

1. Applicants must be United States citizens, nationals, or permanent residents;

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 come from a disadvantaged background;

4. Applicants must have total qualifying educational debt equal to or in excess of 20 percent of their institutional base salary at the time of award (projected to be between July 1 and September 1, 2005). Institutional base salary is the annual amount the organization pays for the individual's appointment, whether the time is spent on research, teaching, patient care, or other activities. Institutional base salary excludes any income that an applicant may earn outside of the duties of the organization, and may not include or comprise any income (salary or wages) earned as a Federal employee;

5. 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);

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 work 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 subparagraph 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, regulations, or HHS/NIH policy. Recipients who receive ECR-LRP awards must conduct their research in accordance with applicable Federal, State and local law (*e.g.*, applicable human subject protection regulations) for the entire period of time;

9. Applicants will not be excluded from consideration 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. Unsuccessful ECR-LRP applicants may reapply in subsequent fiscal years.

The following individuals are ineligible for participation in the ECR-LRP:

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 is obtained:

(a) Armed Forces (Army, Navy, or Air Force) Professions Scholarship Program,

(b) Exceptional Financial Need (EFN) Scholarship Program,

(c) Financial Assistance for Disadvantaged Health Professions Students (FADHPS),

(d) Indian Health Service (IHS) Scholarship Program,

(e) National Health Service Corps (NHSC) Scholarship Program,

(f) National Institutes of Health Undergraduate Scholarship Program (UGSP),

(g) Physicians Shortage Area Scholarship Program,

(h) Primary Care Loan (PCL) Program, (i) Public Health Service (PHS) Scholarship Program, and

(j) 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 work week, are eligible to apply for the ECR-LRP 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.

Selection Process

Upon receipt, applications for both initial and renewal awards will be reviewed for eligibility and completeness. Incomplete or ineligible applications will not be considered. Applications that are complete and eligible will be forwarded for peer review. 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.

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 ensure the award of loan repayment.

The following information is furnished by applicants or others on behalf of applicants (forms are completed electronically at the LRP Web site at <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.

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. 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).

10. Certification of disadvantaged background that verifies the applicant's disadvantaged status and consists of one of the following:

- a. Written statement from the applicant's former health professions school(s) that indicates that the applicant qualified for Federal

disadvantaged assistance during attendance;

- b. Documentation that the applicant received any of the following financial aid: Health Professions Student Loans (HPSL) or Loans for Disadvantaged Student Program; or

- c. Documentation that the applicant received scholarships from the U.S. Department of Health and Human Services (HHS) under the Scholarship for Individuals with Exceptional Financial Need.

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.

6. Biosketch of any supplemental mentors/advisors or laboratory staff member if involved in the training and mentoring of the applicant.

The other 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 that 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 work effort or not less than 20 hours per week based on a 40-hour work week;

- (c) Certifies that the sponsoring entity is a domestic non-profit institution (exempt from tax liability under 26 U.S.C. 501); and

- (d) Provides the applicant's institutional base salary.

Program Administration and Details

Under the ECR-LRP, 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.

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, an 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 that 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:

- Undergraduate, graduate, and health professional school tuition expenses;
- Other reasonable educational expenses required by the school(s) attended, including fees, books, supplies, educational equipment and materials, and laboratory expenses; and
- 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 Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds:

1. Loans not obtained from a U.S. or other government entity, an 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 that 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) (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 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.

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 ECR-LRP expires on December 31, 2004. The Catalog of Federal Domestic Assistance number for the Extramural Clinical Research LRP for Individuals from Disadvantaged Backgrounds is 93.308.

Dated: November 19, 2004.

Elias A. Zerhouni,

Director, NIH.

[FR Doc. 04-26369 Filed 11-29-04; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Loan Repayment Program for Health Disparities Research

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) and the National Center on Minority Health and Health Disparities (NCMHD) announce the 2005 Loan Repayment Program for Health Disparities Research (HDR-LRP or Program). The HDR-LRP provides for the repayment of educational loan debt of up to \$35,000 annually for qualified health professionals conducting

minority health or other health disparities research for domestic non-profit or government entities. In addition, payments equal to 39 percent of the loan repayments are issued to the Internal Revenue Service on behalf of the program participants to offset Federal tax liabilities incurred as a result of participating in the program. The Program may also provide reimbursement for State and local tax liabilities.

The purpose of the HDR-LRP is the recruitment and retention of highly qualified health professionals to research careers that focus on minority health or other health disparity issues. Through this notice, NIH and NCMHD invite qualified health professionals who contractually agree to engage in minority health or other health disparities research for at least two years, and who agree to engage in this area of research for at least 50 percent of their time, *i.e.*, not less than 20 hours per week, to apply for participation in the Loan Repayment Program for Health Disparities Research.

DATES: Interested persons may request information about the HDR-LRP beginning on November 30, 2004.

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 e-mail: Moorej@mail.nih.gov, by fax: 301-402-0169, or by telephone: 301-496-4607 (not a toll-free number). For information regarding the requirements, application deadline dates, and on-line application for the HDR-LRP program, please visit the NIH Loan Repayment Program Web site at <http://www.lrp.nih.gov>, send an e-mail to lrp@nih.gov, call the LRP helpline at 866-849-4047 (toll-free number) or contact the NCMHD Loan Repayment Coordinator, Kenya McRae, at 301-402-1366 (not a toll-free number) or via e-mail: mcraek@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The Minority Health and Health Disparities Research and Education Act of 2000 (Pub. L. 106-525), adds section 485G of the PHS Act to allow the Director, NCMHD, to enter into contracts for loan repayment with appropriately qualified health professionals who agree to conduct minority health or other health disparities research. Under such contracts, qualified health professionals agree to conduct minority health or health disparities research for a minimum of 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