

2,214. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

NIH is herewith requesting that OMB approve the modification of the collection of information simultaneously with the publication of this **Federal Register** notice and the publication of the Program Announcements in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: The Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Stuart Shapiro, Desk Officer for NIH.

Dated: July 13, 2001.

Ruth L. Kirschstein,

Acting Director, NIH.

[FR Doc. 01-18910 Filed 7-27-01; 8:45 am]

BILLING CODE 4140-01-P

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

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) hereby announces the availability of educational loan repayment under the NIH Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (the Program). The Program, 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 (Public Law 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 (Public Law 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 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 invites health professionals, who are from disadvantaged backgrounds and interested in engaging in clinical research for at least two years, to apply for participation in the NIH Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (ECR-LRP). Concurrent with the publication of this notice, NIH is publishing elsewhere in the **Federal Register** Notification of Request for Emergency Clearance for Modification of the information collection, OMB No. 0925-0361, "National Institutes of Health Loan Repayment Programs," to obtain approval for the additional information in connection with the application process, with the comment period to close July 31, 2001.

DATES: Interested persons may request information about the Program beginning on July 30, 2001.

ADDRESSES: Information regarding the requirements and application procedures for the Program may be obtained by calling or writing: National Center on Minority Health and Health Disparities, National Institutes of Health, Democracy II, Suite 800, 6707 Democracy Blvd, MSC 5465, Bethesda, Maryland 20892-5465, Attention: Kenya McRae, telephone (301-402-1366).

SUPPLEMENTARY INFORMATION: The definition of clinical research is found in section 206 of Public Law 106-505, the Public Health Improvement Act, enacted on November 13, 2000: The term clinical research 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 the 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. An "individual from a disadvantaged background" (see 42 CFR 68a.2) is one who: (1) Comes from an

environment that inhibited the individual from obtaining the knowledge, skill and ability required to enroll in and graduate from a health professions school; or (2) 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 changes in the Consumer Price Index, and adjusted by the Secretary for use in all health professions programs. The Secretary periodically publishes these income levels in the **Federal Register**.

Applicants must certify disadvantaged status under the above definition by submitting: (1) A personal statement explaining the applicability of the above definition to his/her circumstances; or (2) a letter in the application package from the individual's former health professions school(s) or other documentation verifying that the applicant qualified for Federal disadvantaged assistance during attendance. Current financial need alone is not sufficient to classify an individual as being from a disadvantaged background.

The Consolidated Appropriations Act, 2001 (Public Law 106-554) was enacted on December 21, 2000, and amends section 487E of the PHS Act to allow the Secretary of HHS, in consultation with the Director of NIH, to enter into contracts for loan repayment with appropriately qualified health professionals from disadvantaged backgrounds who agree to conduct clinical research, at NIH-supported or otherwise funded research sites, but not as employees of NIH. This program is known as the NIH Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (ECR-LRP). Under the contracts, qualified health professionals who are from disadvantaged backgrounds with substantial educational loan debt relative to income 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. The Acting Director of NIH delegated authority for implementation of the Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (ECR-LRP) for fiscal year 2001 to the Director, National Center on Minority Health and Health Disparities (NCMHD), NIH.

Eligibility Requirements

Specific eligibility criteria with regard to participation in the ECR-LRP include the following:

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

(2) Participants must have an M.D., Ph.D., D.O., D.D.S., Sc.D., or equivalent professional degree.

(3) Participants must come from a disadvantaged background. An individual from a disadvantaged background (see 42 CFR 68a.2) is one who: (a) Comes from an environment that inhibited the individual from obtaining the knowledge, skill and ability required to enroll in and graduate from a health professions school; or (b) 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 changes in the Consumer Price Index, and adjusted by the Secretary for use in all health professions programs. The Secretary periodically publishes these income levels in the **Federal Register**. Participants must certify disadvantaged status under the above definition by submitting: (a) A personal statement explaining the applicability of the above definition to his/her circumstances; or (b) a letter in the application package from the individual's former health professions school(s) or other documentation verifying that the applicant qualified for Federal disadvantaged assistance during attendance. Current financial need alone is not sufficient to classify an individual as being from a disadvantaged background.

(4) Participants must have qualifying educational debt in excess of 20 percent of their annual salary, stipend, or compensation at their expected date of program eligibility. The expected date of program eligibility is the date by which the following conditions will be met: (a) An applicant agrees to begin clinical research and (b) the Secretary executes an ECR-LRP contract.

(5) Participants must not be Federal employees.

(6) Participants must have a research sponsor or mentor with experience in the area of proposed research and may be enrolled in a training program or appointed under a temporary (at least two years) or permanent employment mechanism.

(7) Participants must engage in qualified clinical research for a minimum of two years.

(8) Individuals with existing service obligations to Federal, State, or other

entities will not be considered for the ECR-LRP unless and until the existing service obligation is discharged or deferred for the length of Program participation.

(9) Individuals are ineligible who have a Federal judgment lien against their property arising from a Federal debt from receiving Federal funds, until the judgment is paid in full or satisfied.

Application Procedures and Selection Process

Submission of applications for participation in the ECR-LRP by eligible individuals should be made to the NCMHD on behalf of the applicant by the extramural research institution. The application package should include: (1) All required forms, completed, signed and dated; (2) research and training plan; (3) the credentials or curriculum vitae of the applicant and mentor/advisor; and (4) a description of the research/training environment. The NCMHD will provide current deadlines, sources for assistance, and additional details regarding application procedures in an Applicant Information Bulletin.

Individuals may submit their applications to the Director, NCMHD, and qualified applications will be forwarded to the NCMHD Loan Repayment Review Panel (the Panel), chaired by the Deputy Director, NCMHD, for review. The Panel will review, rank, and approve or disapprove all applications submitted to the ECR-LRP.

The Panel will review and select applications for approval based on the merit of the proposed clinical research, the credentials of the applicant and supervisor, and other criteria the Secretary deems appropriate. For example, all of the following contribute to the merit of the application: the quality of the mentoring program, which includes the journal clubs or other groups available to the applicant and the planned conferences and seminars to be attended; the quality of the mentor's research program; the proposed training mechanism; and the research methods and scientific techniques to be taught.

The definition of clinical research used by the Panel can be found in section 206 of Public Law 106-505, the Public Health Improvement Act: The term clinical research 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 epidemiologic or behavioral studies, outcomes research or health services research, or developing new technologies, therapeutic interventions, or clinical trials.

Funds for repayment will only be awarded to Review Panel-approved applications. Priority in funding will be given to qualified health professionals who are from disadvantaged backgrounds and/or who are underrepresented in biomedical/behavioral research, including members from racial and ethnic minority groups and disabled individuals. The emphasis on "clinical research" and on individuals from "disadvantaged backgrounds" highlights the need for the involvement of a cadre of culturally competent physician scientists in clinical research. Such a cadre of clinical investigators can impact the medical processes within their communities and promote the development of clinical research programs that reflect an understanding of the variety of issues and problems that impact health outcomes.

Program Administration and Details

Under the ECR-LRP, the NIH will repay a portion of the extant qualified educational loan debt incurred by health professionals to pay for their undergraduate, graduate, and/or health professional school educational expenses. Upon application, individuals must have total qualified educational debt that exceeds their anticipated annual compensation ("debt threshold") on the date of program eligibility.

Only qualified loan amounts in excess of 50 percent of the debt threshold will be considered for repayment ("repayable debt"). The repayable debt of qualified health professionals will be satisfied at the rate of one-half of the repayable debt per year, subject to a statutory limit of \$35,000 per year, for each year of obligated service. Obligated service requires selected individuals to engage in qualified clinical research for at least 2 years. Following conclusion of the initial two-year contract, participants may apply for renewal contracts to satisfy their remaining repayable debt. These continuation contracts may be submitted and approved on a competitive year-to-year basis, subject to a finding by the NCMHD that the applicant's clinical research accomplishments are acceptable and qualified clinical research continues. Funding of contracts is contingent upon appropriation and/or

allocation of funds from the U.S. Congress and/or the NIH.

Concurrent with the issuance of each loan repayment, a 39% Federal tax payment is issued to compensate participants for the tax liabilities incurred on their loan payments, which are considered taxable income by the IRS. Depending on the availability of funds and the final level of benefits offered, the NCMHD may make additional tax payments, whether they be for Federal or State taxes, for the additional incremental taxes incurred by recipients that are directly attributable to the loan repayment and Federal tax payments.

In return for the repayment of their educational loans, participants must agree to: (1) Engage in clinical research for a minimum requirement of 2 years; (2) pay monetary damages as required for breach of contract; and (3) satisfy other terms and conditions of the ECR-LRP's contract and application procedures.

Applicants must submit a signed contract, prepared by the NIH, agreeing to obligated service at the time they apply for consideration under the ECR-LRP. Substantial monetary penalties will be imposed for breach of contract.

The NIH will repay lenders for the principal, interest, and related expenses (such as the required insurance premiums on the unpaid balances of some loans) of qualified Government (Federal, State, local) and commercial 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 will be authorized for direct payment to lenders, following receipt of: (1) the supervisor's verification of completion of the prior period of obligated service and (2) lender verification of the crediting of prior loan repayments, including the resulting account balances and current account status. The NCMHD will repay loans in the following order unless significant savings would result from repaying loans in a different priority order:

(1) Health Education Assistance Loans (HEAL);

(2) other loans guaranteed by the Federal Government; and

(3) other qualifying loans.

The following loans are NOT repayable under the ECR-LRP:

(1) Loans not obtained from a Government entity or commercial or other chartered lending institution, such as loans from friends and relatives, or other private individuals;

(2) Loans for which contemporaneous documentation is not available; and

(3) Loans, or those portions of loans, obtained for educational or living expenses which exceed a "reasonable" level as determined by a review of the standard school budget or additional contemporaneous documentation for the year in which the loan was made.

In addition, for other programs which provide loans, scholarships, loan repayments, or similar awards in exchange for a future service obligation, the NIH will NOT repay any sums that may result from failure to serve as required or conversion of the obligation to a loan or debt under these programs. This includes, but is not limited to the following:

(1) Physicians Shortage Area Scholarship Program (Federal or State);

(2) National Research Service Award Program;

(3) Public Health Service and National Health Service Corps Scholarship Programs;

(4) Armed Forces (Army, Navy, or Air Force) Health Professions Scholarship Programs; and

(5) Indian Health Service Scholarship Program.

Finally, payments will not be made under the ECR-LRP for loans that participants have already repaid, delinquent loans, loans in default, loans not current in their payment schedule, or loans for which promissory notes have been signed after the program eligibility date and PLUS loans. During lapses in loan repayments, due either to administrative complications or a break in service, ECR-LRP participants are wholly responsible for making payments or other arrangements that maintain loans in a current payment status such that increases in either principal or interest do not occur. Penalties assessed participants as a result of NIH administrative complications may be considered for reimbursement.

Dated: July 13, 2001.

Ruth L. Kirschstein,
Acting Director, NIH.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Loan Repayment Program for Health Disparities Research

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) hereby announces the availability of educational loan repayment under the NIH Loan Repayment Program for Minority Health Disparities Research (HDR-LRP). The NIH HDR-LRP, which was authorized by section 103 of Public Law 106-525, the Minority Health and Health Disparities Research and Education Act of 2000, which added section 485G of the Public Health Service (PHS) Act, provides for the repayment of the educational loan debt of health professionals who have substantial debt relative to income and who agree to conduct minority health disparities research or other health disparities research. Under authority of the extramural HDR-LRP, the "Director of the Center shall establish a program of entering into contracts with qualified health professionals under which such health professionals agree to engage in minority health disparities research or other health disparities 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 purpose of the extramural HDR-LRP is the recruitment of highly qualified health professionals to careers in minority health and other health disparities research. The Program will be administered by the National Center on Minority Health and Health Disparities (NCMHD) of the NIH. Through this notice, the NIH invites health professionals who are interested in engaging in minority health and other health disparities research for at least two years to apply for participation in the extramural HDR-LRP. Concurrent with the publication of this notice, NIH is publishing elsewhere in the **Federal Register** Notification of Request for Emergency Clearance for Modification of the information collection, OMB No. 0925-0361, "National Institutes of Health Loan Repayment Programs," to obtain approval for the additional information in connection with the application process, with the comment period to close July 31, 2001.

DATES: Interested persons may request information about the HDR-LRP beginning on July 30, 2001.

ADDRESSES: Information regarding the requirements and application