

OMB Human Resources and Housing Branch, Attention: Wendy Taylor, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: July 18, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards,

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notification of Request for Emergency Clearance; Modification of OMB Number 0925-0361, "National Institutes of Health Loan Repayment Programs"

SUMMARY: In accordance with section 3507(j) of the Paperwork Reduction Act of 1995, the National Institutes of Health hereby publishes notification of request for Emergency Clearance for modification of the information collection related to the "Loan Repayment Program for Health Disparities Research" and the "Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds," published elsewhere in today's **Federal Register**. The currently approved information collection, "National Institutes of Health Loan Repayment Programs" (OMB No. 0925-0361), permits the NIH to request from applicants information related to eligibility, qualifications, career interests and recommendations necessary to evaluate their applications for repayment of educational indebtedness in return for agreeing to conduct research as an employee of the National Institutes of Health. Public Law 106-525 amended the Public Health Service Act (42 U.S.C. 288-5) by adding a new section 485G to provide repayment of educational loan indebtedness of qualified health professionals who are not Federal employees and who agree to conduct basic, clinical, or behavioral research directly related to health disparities. Public Law 106-554 amended section 487E of the Public Health Service Act (42 U.S.C. 288-5) to allow expansion of the existing program to provide repayment of educational loan indebtedness of qualified health professionals from disadvantaged backgrounds who are not Federal

employees and who agree to conduct clinical research.

To implement these new loan repayment programs, NIH must request additional information from applicants and the institutions that submit applications on their behalf. Specifically, in the case of the Loan Repayment Program for Health Disparities Research, information in the application will also include: (1) A Research Plan—a description of the applicant's proposed role in the research conducted in the extramural laboratory or clinical research setting; (2) A brief statement addressing the applicant's long-range career plan for engaging in research on health disparities; (3) Institutional Assurance of future/current employment/affiliation; (4) Description of Training Environment, including a Training Plan, describing the applicant's mentoring program, the types of training interactions, research methods to be used and scientific techniques to be taught, journal clubs or groups the applicant will join, conferences and seminars to be attended, and a Description of the Advisor's/Supervisor's Research Program, with a description of the current research, listing of research support and a current C.V. with a list of publications.

In regard to the Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds, applicants are required to submit: (1) A Research Plan—a description of the applicant's proposed clinical research assignment, including the applicant's specific responsibilities and roles in conducting the research; (2) Institutional Assurance of future/current employment/affiliation; (3) Description of Training Environment, including a Training Plan, describing the applicant's mentoring program, the types of training interactions, research methods to be used and scientific techniques to be taught, journal clubs or groups the applicant will join, conferences and seminars to be attended, and a Description of the Advisor/Supervisor's Research Program, with a description of the current research, listing of research support and a current C.V. with a list of publications.

The present modification relates to the additional reporting requirement of submission of information and documentation to permit the agency to evaluate the eligibility, qualifications, and overall merit of the applications, including, for example, the quality of the mentoring program, the quality of the mentor/supervisor's research program, the proposed training

mechanism, and the research methods and scientific techniques to be taught.

The modification is essential to the mission of NIH (42 U.S.C. 241 and 282(b)) and pursuant to the statutory mandates of 42 U.S.C. 287c-33 and 42 U.S.C. 288-5a requiring the NIH to establish loan repayment programs for eligible qualified health professionals, not employed by the Federal Government, who enter into contracts with the Secretary of Health and Human Services (HHS) to engage in minority health disparities research and for qualified health professionals from disadvantaged backgrounds, not employed by the Federal Government, who enter into contracts with the Secretary, HHS, to conduct clinical research.

The United States Congress conducted hearings to establish these expansions of the National Institutes of Health Loan Repayment Programs on the basis of which it determined that these measures are essential to the public welfare. In view of the record established in legislative hearings and congressional deliberations, 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**.

Proposed Collection

Title: National Institutes of Health Loan Repayment Programs. *Type of Information Collection Request:* REVISION. *Need and Use of Information Collection:* The additional NEW reporting requirement is needed to permit the agency to evaluate the eligibility, qualifications and overall merit of the applications. *Frequency of Response:* One-time response to accommodate NEW programs. *Affected Public:* Individuals or households; Business or other for-profit; Not-for-profit institutions; State, local or tribal Government. *Type of Respondents:* Loan Repayment Program Applicants; Scientific and Clinical Researchers; Research and Academic Institutions; Lending Organizations and Banks. The annual reporting burden was: *Estimated Number of Respondents:* 990. *Estimated Number of Responses per Respondent:* 1. *Average Burden Hours Per Response:* 1.53. *Estimated Total Annual Burden Hours Requested:* 1,424. The NEW annual reporting burden is as follows: *Estimated Number of Respondents:* 1,540. *Estimated Number of Responses per Respondent:* 1.02. *Average Burden Hours Per Response:* 1.43. *Estimated Total Annual Burden Hours Requested:*

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.

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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

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.