

Supporting Statement A
National Institutes of Health
Loan Repayment Programs (OD)
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Attachments

- Attachment 1: Data Collection Instruments with Instructions
- Attachment 2: Privacy Act System of Records Notice

Abstract of the Supporting Statement

All of the NIH Loan Repayment Programs are designed to attract highly qualified physicians and other scientific or medical personnel to research opportunities at the National Institutes of Health (NIH, Intramural) and Non-NIH sites (Extramural). There are a total of 3 Intramural and 5 Extramural programs. Intramural includes AIDS Research Loan Repayment Program (AIDS-LRP), the General Research LRP (GR-LRP), and the Clinical Research LRP for Individuals from Disadvantaged Backgrounds (CR-LRP). The Extramural programs include Clinical Research LRP for Individuals from Disadvantaged Backgrounds (ECR-LRP), the Pediatric Research LRP (PR-LRP), the Contraception and Infertility Research LRP (CIR-LRP), the Health Disparities Research LRP (HD-LRP), and the Loan Repayment Program Regarding Clinical Researchers (LRP-CR). Data collected through application forms is necessary to determine an applicant's eligibility for the program, including his or her research plans and career interests. The forms presented to the applicant vary based on the application type, Initial/New or Renewal. Each initial applicant is expected to spend approximately 10 hours completing and assembling the application package, and each intramural renewal applicant approximately 8 hours. Both applications require supporting online forms to be completed by their colleagues. The time for completing these forms is included in this document.

Approximately 1,930 initial applicants and 1,285 renewal applicants are expected to submit application packages for an annual burden of 36,329.75 hours.

The cost of these submissions is expected to be approximately \$1,298,341.28. The annualized cost to the Federal Government for administering the Loan Repayment Programs is expected to be \$1,794,667.48. This cost includes administrative support by the Division of Loan Repayment and \$440,439 for the continuing development and maintenance of the LRP Management Information System/Online Application System (MIS/OAS).

Supporting Statement

A. Justification

A.1. Circumstances Making the Collection of Data Necessary

In November 1988, Public Law 100-607 enacted Section 487A of the Public Health Service Act (42 U.S.C. 288-1), which authorized the National Institutes of Health (NIH) to establish the AIDS Research Loan Repayment Program (AIDS-LRP) to attract additional health professionals into research involving AIDS. In June 1993, Public Law 103-43 reauthorized Section 487A and added Section 487C (42 U.S.C. 288-3), which established the General Research Loan Repayment Program (GR-LRP) to attract highly qualified health professionals, particularly physicians and doctoral-level scientists, to conduct research at NIH. Further, Public Law 103-43 also added Section 487E (42 U.S.C. 288-5), which established the Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (CR-LRP) to attract clinical researchers, primarily physicians and dentists, from disadvantaged backgrounds to the NIH. The purpose of these programs is to attract highly qualified physicians, nurses, and scientists to HIV/AIDS research, clinical research, and general research as employees of the NIH by countering the economic disincentives to entering or continuing in biomedical research careers when burdened with the repayment of educational loans.

In 1993, the U.S. Congress also authorized a loan repayment program for appropriately qualified health professionals who are not employees of the NIH. Specifically, the NIH Revitalization Act (Public Law 103-43) added to the PHS Act Section 487B (42 U.S.C. 288-2), which established the Contraception and Infertility Research Loan Repayment Program (CIR-LRP) to recruit qualified health professionals and graduate students who agree to commit to a minimum of 2 years conducting research with respect to contraception and infertility. In 2000, the U.S. Congress authorized three additional loan repayment programs and expanded the

existing CR-LRP for appropriately qualified health professionals who are not employees of NIH or for-profit organizations. Specifically, the Consolidated Appropriations Act of 2001 (Public Law 106-554) amended Section 487E of the PHS Act to allow expansion of the existing CR-LRP to include health professionals who are not employees of the NIH. The expanded program is known as the Extramural Clinical Research LRP for Individuals from Disadvantaged Backgrounds (ECR-LRP). The purpose of the ECR-LRP is to attract highly qualified health professionals from disadvantaged backgrounds to clinical research. The Minority Health and Health Disparities Research and Education Act (Public Law 106-525), Section 485G of the PHS Act (42 U.S.C. 287c-33) authorized the Health Disparities Research Loan Repayment Program (HD-LRP). The purpose of the HD-LRP is to recruit health professionals to minority health disparities and other health disparities research. The Public Health Improvement Act (Public Law 106-505) added Section 487F (42 U.S.C. 288-5a) to the PHS Act, and established a program of entering into contracts with qualified health professionals who agree to conduct clinical research. The purpose of the Loan Repayment Program Regarding Clinical Researchers (LRP-CR) is to recruit and retain highly qualified health professionals as clinical investigators. The Pediatric Research Loan Repayment Program (PR-LRP) is authorized by the Children's Health Act of 2000 (Public Law 106-310), Section 487F (42 U.S.C. 288-6). The PR-LRP offers support to health professionals who agree to conduct research that is directly related to diseases, disorders, and other conditions in children, including pediatric pharmacology as of 2007.

The Division of Loan Repayment has the statutory authorization from the Public Health Service Act necessitating the collection of data for the above-referenced programs. These programs have existing data collections with an OMB control number (OMB No. 0925-0361, expiration date 06/30/08).

A.2. Purpose and Use of the Information Collection

The Loan Repayment Programs are designed to provide repayment of existing eligible loans of up to \$35,000 per year to qualified health professionals performing research in fields

required by the NIH to support its mission. The data collected on individual application forms includes the following:

- Loan data and status, which will be used to determine eligibility of the loan for repayment, program eligibility, payment projections should an LRP contract be awarded, and the Federal Tax Identification Number of the lender or servicer of the loan.
- A personal statement, which will inform reviewers of the applicant's career goals, academic objectives, and research objectives.
- Disadvantaged background documentation (CR-LRP and ECR-LRP only), which will be used to determine an applicant's eligibility for disadvantaged background status.
- Recommendations for inclusion in the program, which will be used to determine the applicant's aptitude to perform clinical, biomedical, contraception/infertility, health disparities, or behavioral research.
- Research activity form, which will be used to determine the applicant's research objectives and his or her role in the scientific research being conducted.
- Assessment of research activities form, which will be used to describe the type of training interactions that an applicant has with his or her advisor, sponsor, or supervisor; the training mechanisms to be used; and the research resources and opportunities available to the applicant.
- An assurance from the extramural institution (for individuals applying to the CIR-LRP, ECR-LRP, HD-LRP, LRP-CR, or PR-LRP) that the applicant will be provided the necessary time and resources to engage in the named research project if a loan repayment contract is awarded as a result of this application.

Applications are expected to be received from up to 1,675 initial applicants and 800 renewal applicants annually. Copies of the application forms and instructions are contained in Attachment 1: Data Collection Instruments with Instructions. The URL for LRP applications is

www.lrp.nih.gov. The forms attached are for OMB review purposes only; applicant information will not be collected on paper.

Since receiving approval for the online application forms in 2005, the Division of Loan Repayment has continued to receive a steady number of applications during each cycle. The forms have remained unchanged other than as described below. Applicant and Colleagues have responded positively to the usability of the online forms.

A.3. Use of Information Technology and Burden Reduction

Application forms and information materials are available online and must be submitted electronically through the LRP Internet site at www.lrp.nih.gov. An applicant can also use the toll-free LRP Helpline at 1-866-849-4047 to request assistance and advice on applying.

The LRP Web site is hosted by the NIH Office of the Director's Office of Information Technology and has been developed to ensure data security and integrity. Data moving across the open Internet from the applicant to the Web server (Microsoft Internet Information Server) are encrypted using Secure Sockets Layer (SSL) 128-bit encryption. The Web server then stores the data on a Microsoft SQL Server located on a private network. The logical and physical security of the computing equipment is protected by NIH Police, a secure server environment, and other security measures. A receipt with an application tracking number is provided to the applicant at the time the full application is submitted.

A.4. Efforts to Identify Duplication and Use of Similar Information

The information collected on the Loan Repayment Program application forms cannot be obtained from any other sources.

A.5. Impact on Small Businesses or Other Small Entities

This information collection will have a minimal impact on banks, colleges, and universities. These entities will be asked to read and verify the information supplied by the applicant. Although physicians can be considered small businesses, those physicians applying for the loan repayment programs are involved in AIDS, clinical, pediatric, contraception and infertility, health disparities, or general research and are not likely to fall into this category. For all respondents, the information being requested has been held to the minimum for the required use.

A.6. Consequences of Collecting the Information Less Frequently

In addition to the application for a 2- or 3-year initial award, participants can submit annual renewal applications for 1 or 2 years after the expiration of the initial award to continue to receive loan repayments. The renewal application is used to assess and prioritize continued program support. Collecting the information less frequently would not allow NIH staff the opportunity to analyze the status of the programs or their participants.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This project is in compliance with all provisions of 5 CFR 1320.5.

A.8. Comments in Response to the 60-Day Federal Register Notice and Efforts to Consult Outside Agency

The 60-day *Federal Register* notice appeared in Vol. 72, No. 246, published December 26, 2007, pages 73030-73031. No responses to the notice were received.

Before publication, the Division of Loan Repayment consulted with the NIH Extramural Activities Working Group concerning programmatic and policy issues associated with the implementation of the extramural Loan Repayment Programs. The members of the NIH

Extramural Activities Working Group are appointed by the NIH Director and the Committee is co-chaired by the Deputy Director for Extramural Research and the Director, National Center for Complimentary and Alternative Medicine. This committee is comprised of institute and center directors and scientific administrators. Previously, the NIH consulted with individuals who are representative of the types of applicants, recommenders, and advisors who will complete the application forms. Those individuals are listed in Table A.8-1.

Table A.8-1. Individuals Consulted Prior to OMB Publication

Name, Title, and Affiliation	Consultation Date	Telephone Number
Sherry Mills, M.D., M.P.H., Acting Director, Office of Extramural Programs, NIH	December 2007	(301) 435-2687
Suman King, Ph.D., Director, Division of Loan Repayment, NIH	December 2007	(301) 594-3234
Patricia Cole, Ph.D., Director, Intramural Loan Repayment Program, NIH	December 2007	(301) 402-1283
Stephen J. Boehlert, Director of Operations, Division of Loan Repayment, NIH	December 2007	(301) 451-4465
Dr. Eric H. Kossoff, Assistant Professor, Johns Hopkins Hospital	December 2004	(410) 683-1428
Barbara L. Jones, Assistant Professor, University of Texas at Austin	December 2004	(512) 475-9367
Igor Matushansky, Clinical Fellow, Memorial Sloan Kettering Cancer Center	December 2004	(212) 639-2282
Mansoureh Tajik, Postdoctoral Fellow, University of North Carolina at Chapel Hill	December 2004	(919) 966-8650
Jeff M. Drazen M.D., Editor in Chief, New England Journal of Medicine	December 2004	(781) 434-7870
Esteban Gonzalez Burchard M.D., Assistant Professor, UCSF	December 2004	(415) 206-3491
Jill Suzanne Barnholtz-Sloan, Assistant Professor, H. Lee Moffitt Cancer Center and Research Institute	December 2004	(813) 745-6531
Laura M. Justice, Ph.D., Assistant Professor, University of Virginia	December 2004	(434) 924-7583
John M. Freeman, Professor of Neurology and Pediatrics, Johns Hopkins University	December 2004	(410) 955-9100
Janice C Froehlich, Ph.D., Professor of Medicine, Indiana University School of Medicine	December 2004	(317) 274-1347
Thomas Henry Brandon Ph.D., Professor, University of South Florida	December 2004	(813) 632-1750
Art Skoultchi, Professor/Chair, Yeshiva University	December 2004	(718) 430-2169
Robert G Maki, Assistant Member, Memorial Sloan Kettering Cancer Center	December 2004	(212) 639-5720
Dean Sheppard, Professor, UCSF	December 2004	(415) 514-4269
Michael J Joyner M.D., Professor, Mayo Clinic	December 2004	(507) 255-4288

A.9. Explanation of Any Payment or Gift to Respondents

No gifts or payments will be made to applicants for completing the application forms.

A.10. Assurance of Confidentiality Provided to Respondents

The data collected for the Loan Repayment Programs are maintained by the Division of Loan Repayment primarily for the purpose of determining an applicant’s eligibility for these programs. The data may also be used by the NIH for evaluating program performance.

Each application package includes a Confidentiality and Privacy Act Notice. All information collected through the NIH loan repayment program application forms will be in compliance with the Privacy Act of 1974. Data gathered on the following forms are maintained in a Privacy Act System of Records, DHHS 09-25-0165:

- Applicant Information form (NIH 2674-1)
- Personal Statement form (NIH 2674-2)
- Recommendations form (NIH 2674-3)
- Loan Information form (NIH 2674-4)
- IC Recommendation for LRP Funding form (NIH 2674-5)
- Research Activities form (NIH 2674-6)
- Assessment of Research Activity form (NIH 2674-7)
- Research Accomplishments form (NIH 2674-8)
- Certifications for Online Applications form (NIH 2674-9)
- Institutional Contact form (NIH 2674-10)
- Disadvantaged Background Documentation form (NIH 2674-11)
- NIH Loan Repayment Program Contract (NIH 2674-12)
- “Colleague” Recommendation Form (NIH 2674-13)
- Assessment of Research Accomplishments form (NIH 2674-14)
- Apply Here/Start of Application (NIH 2674-15)
- Institutional Information form(NIH 2674-16)
- Loan Data Verification (NIH 2674-17) *
- Citizenship Information form (NIH 2674-18)
- Funding Information form(NIH 2674-19)

* This form is used when an existing participant changes lenders or consolidates loans.

The last update was published in the *Federal Register* on February 8, 2002. This document is in the process of being updated with publication expected in the Spring of 2008. Both documents are contained in Attachment 2: Privacy Act System of Records Notice.

Information provided on each applicant and participant is retained and disposed of under the authority of the NIH Records Control Schedule. Participant's records are maintained for 6 years after closeout. This is the minimum retention period for records of a financial nature. Data gathered from program applicants and participants are maintained in file folders and computer storage media. Access is limited to authorized personnel in the performance of their duties.

A.11. Justification for Sensitive Questions

The questions contained in the application and renewal forms for the intramural and extramural Loan Repayment Programs pertain only to information necessary to allow the NIH to determine applicant's eligibility for these programs and aptitude for biomedical research. The information does contain personally identifiable information such as the name, Social Security Number and address. Some of the information being collected is meant for use in program evaluation. The purposes of the information collection are described to applicants in the Confidentiality and Privacy Act Notice contained in the instructions.

A.12. Estimates of Hour Burden Including Annualized Hourly Costs

Approximately 1,930 initial applicants and 1285 renewal applicants are expected to complete the application forms: 30 initial applicants from the intramural programs (GR-LRP, AIDS-LRP, and CR-LRP); 1,900 initial applicants from the extramural programs (CIR-LRP, ECR-LRP, HD-LRP, LRP-CR and PR-LRP); and 1225 renewal applicants from the extramural programs and 60 from the intramural programs. Each intramural applicant is expected to spend

approximately 10 hours and 7 minutes on completing and assembling the information for the application; each extramural applicant is expected to spend 10 hours and 21 minutes; each intramural renewal applicant is expected to spend 7 hours and 25 minutes, while each extramural renewal applicant is expected to spend 8 hours and 35 minutes. Three recommendations will be required for each applicant. Each person completing a recommendation for an applicant is expected to require 20 minutes to do so. Each advisor, sponsor, or supervisor is expected to require 30 minutes completing the Assessment of Research Activity form. In addition, each advisor, sponsor or supervisor is required to complete the Assessment of Research Accomplishments for Renewal applicants only. The projection of the intramural estimates for initial applicants is shown in Table A.12-1; the projection of the extramural estimates for initial applicants is shown in Table A.12-2; the projection of the intramural estimates for renewal applicants is shown in Table A.12-3; and the projection of the extramural estimates for renewal applicants is shown in Table A.12-4.

Table A.12-1. Estimates of Hour Burden for Initial Applicants to Intramural Programs

Type of Respondents	Number of Respondents	Frequency of Response	Average Hours per Response	Annual Hour Burden
Applicant	30	1.0	10.11	303.30
Advisors/Supervisors	30	1.0	0.50	15.00
Recommenders	90	1.0	0.33	30.00
Financial Institutions	10	1.0	1.25	13.00
Totals	160			361.30

Table A.12-2. Estimates of Hour Burden for Initial Applicants to Extramural Programs

Type of Respondents	Number of Respondents	Frequency of Response	Average Hours per Response	Annual Hour Burden
Applicant	1,900	1.0	10.35	19,665.00
Advisors/Supervisors	1,750	1.0	0.50	875.00

Recommenders	5,700	1.0	0.33	1,881.00
Financial Institutions	300	1.0	1.25	375.00
Totals	9,650			22,796.00

Table A.12-3. Estimates of Hour Burden for Renewal Applicants to Intramural Programs

Type of Respondents	Number of Respondents	Frequency of Response	Average Hours per Response	Annual Hour Burden
Applicant	60	1.0	7.42	445.20
Advisors/Supervisors	60	1.0	1.33	80.00
Totals	120			525.20

Table A.12-4. Estimates of Hour Burden for Renewal Applicants to Extramural Programs

Type of Respondents	Number of Respondents	Frequency of Response	Average Hours per Response	Annual Hour Burden
Applicant	1,225	1.0	8.58	10,511.00
Advisors/Supervisors	925	1.0	1.00	925
Recommenders	3,675	1.0	0.33	1,213.00
Totals	5,825			12,649.00

The cost to the applicant for completing the application is based on the average hourly wage for an NIH entry-level tenure-track scientist (\$30.88 per hour). The cost for completing the Loan Information form by each of the applicant's financial institution is based on 75 minutes of clerical time (at \$19.32 per hour) to retrieve data from the institution's files and complete the form. This rate is based on midlevel financial technician salary. Typically, recommenders and advisors will be senior scientists of NIH institutes or centers for intramural programs and equivalent scientists in biomedical research at academic research institutions and medical schools. The cost for the recommenders to complete the Recommendation form is based on 20 minutes at an average hourly rate of \$66.94. The cost for the extramural advisors to complete the Assessment of Research Activity form is based on 30 minutes at an average hourly rate of

\$66.94. A projection of these estimates is shown in Table A.12-5 for initial intramural respondents, Table A.12-6 for initial extramural respondents, Table A.12-7 for renewal intramural respondents and Table A.12-8 for renewal extramural respondents.

Table A.12-5. Annualized Cost to Initial Intramural Respondents

Type of Respondents	Number of Respondents	Hourly Wage Rate	Average Hours per Response	Total Cost
Applicant	30	\$30.88	10.11	\$9,365.90
Advisors/Supervisors	30	\$66.94	0.50	\$1,004.10
Recommenders	90	\$66.94	0.33	\$1,988.12
Financial Institutions Professional/Clerical Prorated	10	\$19.32	1.25	\$241.50
Total Respondent Cost \$12,599.62				

Table A.12-6. Annualized Cost to Initial Extramural Respondents

Type of Respondents	Number of Respondents	Hourly Wage Rate	Average Hours per Response	Total Cost
Applicant	1,900	\$30.88	10.35	\$607,255.20
Advisors/Supervisors	1,750	\$66.94	0.50	\$58,572.50
Recommenders	5,700	\$66.94	0.33	\$125,914.14
Financial Institutions Professional/Clerical Prorated	300	\$19.32	1.25	\$7,245.00
Total Respondent Cost \$798,986.84				

Table A.12-7. Annualized Cost to Renewal Intramural Respondents

Type of Respondents	Number of Respondents	Hourly Wage Rate	Average Hours per Response	Total Cost
Applicant	60	\$30.88	7.42	\$13,747.78
Advisors/Supervisors	60	\$66.94	1.33	5,341.81

Type of Respondents	Number of Respondents	Hourly Wage Rate	Average Hours per Response	Total Cost
Total Respondent Cost \$19,089.59				

Table A.12-8. Annualized Cost to Renewal Extramural Respondents

Type of Respondents	Number of Respondents	Hourly Wage Rate	Average Hours per Response	Total Cost
Applicant	1,225	\$30.88	8.58	\$324,564.24
Advisors/Supervisors	925	\$66.94	1.00	61,919.50
Recommenders	3,675	\$66.94	0.33	\$81,181.49
Total Respondent Cost \$467,665.23				

A.13. Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no additional costs associated with the collection of this information.

A.14. Annualized Cost to the Federal Government

The annualized cost to the Federal Government for administering the Loan Repayment Programs is expected to be \$1,794,667.48. The Division of Loan Repayment will provide ongoing administrative support for all eight programs, as well as the following:

- Receipt of applications.
- Application review support (intramural programs only).
- Administration of loan repayment processing, including research service verifications.

This work by the Division of Loan Repayment will require the majority of the time for the following:

- One Operations Manager
- Two Financial Analysts

- One Budget Analyst
- Three Auditors
- One Program Analyst
- Three Accounting Technicians
- Four Program Assistants

The annualized cost also includes \$440,439 for the continuing development and maintenance of the LRP Management Information System/Online Application System (MIS/OAS).

A.15. Explanation for Program Changes or Adjustments

The burden hours for the eight programs have been increased by 7,291.31. This number reflects adjustments for the greater number of initial applicants for the extramural programs (from 1,600 applicants to 1,900 applicants), as well as a greater number of renewal applicants for the extramural program (from 800 to 1,225 applicants). These changes will bring the total burden hours for the eight programs to 36,331.5 hours.

The following changes are being proposed to the individual forms. These changes are not expected to impact the burden time specified in the forms.

- Applicant Information form (NIH 2674-1)
 - Section 5: Federal Government Employment
 - Modify the text of the two questions
 - Section 6: Service Obligation
 - Remove Organizational Name, Organizational Address, Contact name, Telephone Number, and Email address.
 - Update instructional text
 - Section 7: Voluntary Disclosures:
 - Add Question “How did you learn about the NIH Loan Repayment

Programs?”

- Reformat the RNO to be compliant with OMB standards regarding ethnicity and race.
- Loan Information form (NIH 2674-4)
 - Remove header text “Section 1” and renumbered the subsequent sections
 - Change text from “Current Payoff Amount” to “Payoff Balance”
 - Add “Interest Type” field
- Research Activities form (NIH 2674-6)
 - Add Shortened/General Research Title
- Institutional Contact form (NIH 2674-10)
 - Add a drop down list of frequent contacts for the applicant to select from
- Apply Here/Start of Application (NIH 2674-15)
 - Modified to accommodate the new NIH Security requirements requiring each applicant to register and set up their own password.
- Institutional Information (NIH 2674-16)
 - Reformatted screen for readability

A.16. Plans for Tabulation and Publication and Project Time Schedule

No statistical analyses will be published using the data collected in these applications.

A.17. Reason(s) Display of OMB Expiration Date Is Inappropriate

The OMB expiration date will be displayed.

A.18. Exceptions to the Paperwork Reduction Act Submissions

There are no exceptions to the Paperwork Reduction Act Submissions.

Attachment 1

Data Collection Instruments with Instructions

Attachment 2

Privacy Act System of Records Notice