

Support Statement A
National Institutes of Health
Loan Repayment Programs (OD)
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This submission is a Revision.

Yellow highlights indicate changes from the 2014 submission.

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Abstract of the Supporting Statement

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 three Intramural and five Extramural programs. Intramural includes AIDS Research Loan Repayment Program (AIDS-LRP), the General Research LRP (GR-LRP), which includes a program for the Accreditation Council for Graduate Medical Education (ACGME) Fellows, 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 Clinical Research LRP (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.

Supporting Statement

A. Justification

A.1. Circumstances Making the Collection of Data Necessary

This is an extension of a currently approved collection, OMB Control #0925-0361, with an expiration date of **06/30/2017**. 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 464z-5 of the PHS Act (42 U.S.C. 285t-2) 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 Clinical Research LRP (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 06/30/17).

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.
- **Reference letters** 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 **1,690 initial applicants and 1,040 renewal applicants annually**. Copies of the application forms and instructions will be submitted with this request. The URL for the LRP application is www.lrp.nih.gov. The forms attached are for OMB review purposes only; applicant information will not be collected on paper.

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 Web site at www.lrp.nih.gov. An applicant may contact the LRP Information Center at 866-849-4047 or lrp@nih.gov 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.

The data provided in the NIH LRP application, including personally identifiable information, are subject to The Privacy Act of 1974 (5 USC 552a). The full PIA is available in the DHHS ProSight tool.

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. 81, No. 33, published February 19, 2016, pages 8514-8516. No responses were received.**

Because there were no substantive changes to the statement since its initial publication on February 10, 2011 in Vol. 76, No. 28 of the Federal Register (pages 7570-7571), OMD did not consult with any internal or external resources. However, in 2015, the Division of Loan Repayment consulted with the directors of the intramural and extramural programs and individuals who are representative of the types of applicants, recommenders, and advisors who will complete the application forms.

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, which is also located on our website at http://www.lrp.nih.gov/privacy_policy/index.aspx. 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, <https://oma.od.nih.gov/forms/Privacy%20Documents/PAfiles/0165.htm>:

- Applicant Information form (NIH 2674-1)
- Personal Statement form (NIH 2674-2)
- **List of Recommenders 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)
- **Profile Information form** (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)
- **Eligibility Checklist (NIH 2674-20)**

** This form is used when a participant adds a loan, changes lenders or consolidates loans.*

Information provided on each applicant and participant is retained and disposed of under the authority of the NIH Records Control Schedule. Participants' 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 an 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. There is no specific Confidentiality Certificate: information is private to the extent permitted by law.

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

Approximately 1,650 initial applicants from the extramural programs (CIR-LRP, ECR-LRP, HD-LRP, LRP-CR and PR-LRP) are expected to spend approximately 11 hours on completing and assembling the information for the application. Approximately 40 initial applicants from the intramural programs (GR-LRP, AIDS-LRP, and CR-LRP) are expected to spend approximately 10 hours on completing and assembling the information for the application. Additionally, approximately 1,000 extramural renewal applicants are also expected to spend approximately 8 hours to complete the application process. An additional 40 intramural renewal applicants are expected to spend approximately 7 hours to complete the application process. All

intramural applicants are expected to take 1 fewer hour to complete the application process compared to their extramural counterparts because intramural applicants are not asked to complete the Institutional Contact form (NIH 2674-10) and the Funding Information form (NIH 2674-19).

On average, there are 3 recommenders for each applicant (except for renewal applicants to Intramural programs), for each initial and extramural renewal applicant the total number of recommenders is approximately 8,070, all of whom will be required to write reference letters (no recommendation is required for intramural renewal applicants). Each recommender completing a reference letter for an applicant is expected to expend 30 minutes per application. Each intramural applicant also has an advisor/supervisor, to total 80 respondents. Each intramural advisor/supervisor is expected to utilize 30 minutes to review and provide concurrence or non-concurrence on the Assessment of Research Activity form, which is provided by all applicants. Approximately 90% of extramural initial applicants and 75% of extramural renewal applicants are mentored research scientists, which account for 2,230 advisors/supervisors. Discussions with financial institutions will vary on a case-by-case basis, contingent upon the information required to confirm the eligibility of the applicants' loans (an average of 100 financial institutions for extramural programs and 8 financial institutions for intramural programs).

Respondents of all types for Initial Applicants to Intramural Programs total 208 and account for an annual burden of 502 hours (Table A. 12-1). Respondents of all types for Initial Applicants to Extramural Programs total 8,180 and account for an annual burden of 22,130 hours (Table A. 12-2). Respondents of all types for Renewal Applicants to Intramural Programs total 80 and account for an annual burden of 360 hours (Table A. 12-3). Respondents of all types for Renewal Applicants to Extramural Programs total 4,750 and account for an annual burden of 10,250 hours (Table A. 12-4). Total respondents for all programs sums 13,218 and accounts for

a grand total annual burden of 33,242 hours. This will be a decrease in burden of 1,683 hours and a reduction of 150 applicants in the extramural programs.

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	40	1	10	400
Advisors/Supervisors	40	1	1	40
Recommenders/Institution Contacts	120	1	30/60	60
Financial Institutions	8	1	15/60	2
Totals	208	208		502

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	1,650	1	11	18,150
Advisors/Supervisors	1,480	1	1	1,480
Recommenders/Institution Contacts	4,950	1	30/60	2,475
Financial Institutions	100	1	15/60	25
Totals	8,180	8,180		22,130

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	40	1	7	280
Advisors/Supervisors	40	1	2	80
Totals	80	80		360

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	1,000	1	8	8,000
Advisors/Supervisors	750	1	1	750
Recommenders/Institution Contacts	3,000	1	30/60	1,500
Totals	4,750	4,750		10,250

The cost to the applicant for completing the application is based on the average hourly wage for an NIH entry-level tenure-track scientist (\$34.03 per hour). 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 30 minutes at an average hourly rate of \$72.03. The cost for the extramural advisors to complete the Assessment of Research Activity form is based on 60 minutes at an average hourly rate of \$72.03. 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. All cost reported was obtained from the BLS' website:

<http://www.bls.gov/ooh/education-training-and-library/postsecondary-teachers.htm>.

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	40	\$34.03	10	\$13,612.00
Advisors/Supervisors	40	\$72.03	1	\$2,881.20
Recommenders	120	\$72.03	30/60	\$4,321.80
Total Respondent Cost				\$20,815.00

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	1,650	\$34.03	11	\$617,644.50
Advisors/Supervisors	1,480	\$72.03	1	\$106,604.40
Recommenders	4,950	\$72.03	30/60	\$178,274.25
Total Respondent Cost				\$902,523.15

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	40	\$34.03	7	\$9,528.40
Advisors/Supervisors	40	\$72.03	2	\$5,762.40
Total Respondent Cost				\$15,290.80

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	1,000	\$34.03	8	\$272,240.00
Advisors/Supervisors	750	\$72.03	1	\$54,022.50
Recommenders	3,000	\$72.03	30/60	\$108,045.00
Total Respondent Cost				\$434,307.50

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 \$1,659,000 which includes \$948,750 for the continuing development and maintenance of the LRP Management Information System/Online Application System (LRP Central) and \$710,250 for staff and contractor salaries. The Division of Loan Repayment will provide ongoing administrative support for all eight LRP programs. That includes application receipt/support and the eligibility and financial vetting.

This work by the Division of Loan Repayment will require a portion of the time from the following:

- Director
- Operations Director
- Three Program Analysts

- Two Financial Analysts
- Two Support Specialists
- One Project Manager
- Two Senior Analysts
- One Administrative Assistant
- **Four** Analysts – DLR Business Operations
- One Communications Analyst

Table A.14-1. Annualized Cost to the Federal Government

Staffing	Task	Annualized Cost
DLR	Director (5% time for 12 months)	\$ 8,750
	Operations Director (10% time for 12 months)	\$ 18,600
	Three Program Analysts (25% time for 12 months)	\$ 97,500
	Two Financial Analysts (30% time for 12 months)	\$ 66,000
	Two Support Specialists (30% time for 12 months)	\$ 46,500
Contractor	One Project Manager (20% time for 12 months)	\$ 49,000
	Two Senior Analysts (30% time for 12 months)	\$ 105,000
	One Administrative Assistant (40% time for 12 months)	\$ 59,200
	Six Analysts - DLR Business Operations (35% time for 12 months)	\$ 207,200
	One Communications Analyst (30% time for 12 months)	\$ 52,500
DLR and Contractor Total		\$ 710,250

IT	Part-time IT Manager (75% time for 12 months)	\$ 29,250
	Three IT Developer (75% time for 12 months)	\$ 521,250
	IT Technical Lead (75% time for 12 months)	\$ 197,250
	QA/Tester/Analyst Lead (75% time for 12 months)	\$ 126,750
	Web Designer /Section 508/ Content Updates (75% time for 12 months)	\$ 72,250
IT Total		\$ 948,750

A.15. Explanation for Program Changes or Adjustments

Since receiving approval for the online application forms in 2014, the Division of Loan Repayment had a slight decline in the number of applications received each cycle. Questions, required information, and requested documents remain largely unchanged. Improvements were made to the structure and appearance of online forms to provide applicants with a better user experience. Information collected from the Applicant Information form (NIH 2674-1) will now be spread over three online sections (tabs) for an improved user experience. Although there are no expected changes in the recommenders' burden, there is a difference in how DLR will collect information from recommenders. Each applicant will continue to ask three recommenders to submit a recommendation on their behalf. However, recommenders will no longer be asked to complete a recommendation form (NIH 2674-13) to answer questions or provide short answers about the applicants. Going forward, recommenders will be asked to write a reference letter that comments on the applicant's research skills and abilities. A general eligibility checklist (NIH 2674-20) was added to the start of the application to reduce the probability of ineligible individuals working through the application only to learn of their disqualification after submitting the application. Several existing forms were strategically grouped under different online screens (tabs) within the application to provide applicants with a better flow as they work through their applications. Redundant questions or statements were eliminated.

The burden hours for the eight programs have decreased by 1,683 hours. This number reflects adjustments for the fewer number of initial applicants for the extramural programs from 1,800 applicants to 1,650 applicants (there is no expected change in the number of applicants for the intramural programs or any of the other respondent types). These changes will bring the total burden hours for the eight programs to 33,242 hours.

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

The data gathered during the annual application cycle is used for determining program eligibility and making awards. However, summary application data may be used for various reports within NIH, published in the Annual Reports, and/or used for periodic evaluation studies of program effectiveness.

The anticipated schedule for our annual application cycle is listed below:

Date	Activity
1-Sep-16 to 15-Nov-16	LRP Application Period
15-Nov-16	Deadline for Letters of Recommendation to be Submitted for Applicants
February-May	Application Peer Review
May	Initial Selection
May-July	Financial Vetting
Mid-July	Final Funding Decisions and Recipient Notification
August-September	Contract Signing
October	First Payment to Lender

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.