

Supporting Statement A for

National Institutes of Health Loan Repayment Programs, OD

OMB# 0925-0361, expiration date 8/31/2019

Date: (insert date after the 60-day comment period)

Check off which applies:

- New
- Revision
- Reinstatement with Change
- Reinstatement without Change

- Extension
- Emergency
- Existing w/o OMB approval

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Attachments (save file names to match what is being referenced: (ex: x.baseline; y.screener)

Attachment 1: HHS Approved – LRP Privacy Impact Assessment 2018.11.30

Attachment 2: Applicant

Attachment 3: Recommender

Attachment 4: Institutional Business Officer

Attachment 5: NIH LRP Coordinator

A. Justification

Abstract:

The NIH Loan Repayment Programs (LRPs) 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). Currently there are three Intramural and five Extramural subcategories. Intramural subcategories include AIDS Research, Clinical Research for Individuals from Disadvantaged Backgrounds, and General Research. Extramural subcategories include Clinical Research, Pediatric Research, Contraception and Infertility Research, Health Disparities Research, and Clinical Research for Individuals from Disadvantaged Backgrounds. Data collected through application forms is necessary to determine an applicant's eligibility for the program, including the applicant's research plans and career interests.

A.1 Circumstances Making the Collection of Information Necessary

This is an extension of a currently approved collection, OMB Control #0925-0361, with an expiration date of 08/31/2019. 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 (LRP-PR) 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 21st Century Cures Act (Public Law 114-255) amended Section 487A of the Public Health Service Act to consolidate all NIH Intramural Loan Repayment Programs (Section 487A) with AIDS-LRP, CR-LRP, and GR-LRP as subcategories. The 21st Century Cures Act also amended Section 487B of the Public Health Service Act to consolidate all NIH Extramural Loan Repayment Programs with LRP-CIR, LRP-CR, LRP-HD, LRP-IDB, and LRP-PR as subcategories.

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 08/31/19).

A.2 Purpose and Use of the Information Collection

The LRPs are designed to provide repayment of existing eligible loans of up to \$50,000 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:

- Applicant, Employment, and Affiliation Information, which will be used for important administrative purposes. Gender, race, ethnicity, and disability status are collected here. Applicants' employers must be a domestic, nonprofit organization to meet NIH LRP eligibility requirements.
- Education and Training Information, which shows an applicant's academic and training history as well as a list of conferred degrees and post-doctoral fellowships. Most applicants are required to hold an M.D., Ph.D., or similar doctoral-level degree to qualify for an award.
- 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.
- 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.
- 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.
- Disadvantaged background documentation, which will be used to determine an applicant's eligibility for disadvantaged background status if applying under the Clinical Research for Individuals from Disadvantaged Backgrounds subcategory.
- An assurance from the extramural institution (for individuals applying to the Extramural LRPs) 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.

In 2017, NIH requested non-substantive changes to this information collection to improve the user's experience (e.g., adoption of electronic signatures) and reduce instances of user error (e.g., typo in email address, upload of incorrect files). In 2018, NIH requested non-substantive changes to this information collection by moving the Upload button for the Mentor Biosketch and an additional colleague (optional) to provide a single destination for Applicants to upload documents. Additionally, we improved the process of identifying applicants' research supervisors and primary mentors by including their organization and position title on the form. In 2019, we added an optional question regarding an applicant's status as an individual from a health disparity population to ensure that no fewer than 50 percent of the Health Disparities Research LRP contracts are for members of a health disparity population. We are utilizing a skip logic so that this question will only appear on the form if an applicant selects the Health Disparities Research LRP (it will not be visible to individuals applying to any of the other NIH LRPs). Due to these changes, the total burden hours are estimated at 27,481 hours, a decrease of 5,761 burden hours since 2016.

Applications are received on annual basis and used to review and determine an applicant's eligibility for the program. 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. OMB clearance is requested for three years.

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 website at www.lrp.nih.gov. Applicants may contact the LRP Information Center at 866-849-4047 or lrp@nih.gov to request assistance and advice on completing the application forms.

The LRP website 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).

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

The information collected on the LRP 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 colleges, universities, and financial institutions. These entities will be asked to verify information provided by the applicant. Although physicians can be considered small businesses, these physicians are in private practice and henceforth are not eligible to apply for the NIH LRPs. 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, awardees can submit 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 prevent NIH staff from being able to properly analyze the status of the programs or their participants.

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

This information collection follows all provisions of 5 CFR 1320.5.

A.8.1 Comments in Response to the Federal Register Notice

The 60-day *Federal Register* notice was published on May 21, 2019 in Vol. 84, No. 98, pages 23060-23061. **No responses were received.**

A.8.2 Efforts to Consult Outside Agency

OMD did not consult with any internal or external resources.

A.9 Explanation of Any Payment of Gift to Respondents

No gifts or payments will be made to applicants for completing and/or submitting the NIH LRP application forms.

A.10 Assurance of Confidentiality Provided to Respondents

The data collected for the NIH LRPs 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 this collection will be in compliance with the Privacy Act of 1974 and are maintained in a Privacy Act System of Records, DHHS 09-25-0165, <https://oma.od.nih.gov/forms/Privacy%20Documents/PAfiles/0165.htm>.

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 NIH LRP application 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 applicant's 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.12.1 Estimates of Hour Burden Including Annualized Hourly Costs

Approximately 1,650 initial applicants from the extramural program are expected to spend 8 hours and 25 minutes to complete and assemble their information for the application. Approximately 40 initial applicants from the intramural programs are expected to spend 7 hours and 40 minutes to complete and assemble their information for the application. Additionally, approximately 1,000 extramural renewal applicants are also expected to spend 8 hours and 20 minutes to complete the application process. An additional 40 intramural renewal applicants are expected to spend 7 hours and 35 minutes to complete the application process. All intramural applicants are expected to require less time 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). Respondents of all application types account for an annual burden total of 21,840 hours.

On average, there are four recommenders for each applicant (except for Intramural renewal applicants since recommendations are not required for Intramural renewal applicants), the total number of recommenders is approximately 10,760, all of whom will be required to write reference letters. Each recommender completing a reference letter for an applicant is expected to expend 30 minutes per application for an annual burden total of 5,380 hours.

Institutional Contacts represent the applicants' employing institutions and are asked to complete the Institution Contact form (NIH 2674-10), which confirms the applicant's citizenship and protected time for research, for each extramural applicant. Each institutional contact is expected to expend 5 minutes per application for an annual burden total of 221 hours.

NIH LRP Coordinators are required to certify that the applicant has an employment offer with NIH for at least 2 years (AIDS and Clinical subcategories) or 3 years (General subcategory) for each intramural applicant. Each NIH LRP Coordinator is expected to expend 5 minutes per application for an annual burden total of 40 hours.

Total respondents for all programs sum 16,220 and account for a grand total annual burden of 27,481 hours, as shown in Table 12-1.

Table 12-1 Estimated Annualized Burden Hours

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Time Per Response (in hours)	Total Annual Burden Hours
Initial Extramural Applicants	1,650	1	8	13,200
Renewal Extramural Applicants	1,000	1	8	8,000
Initial Intramural Applicants	40	1	8	320
Renewal Intramural Applicants	40	1	8	320
Recommenders	10,760	1	30/60	5,380
Institutional Business Officers	2,650	1	5/60	221
NIH LRP Coordinators	80	1	30/60	40
Total	16,220	16,220		27,481

A.12.2 Annual Cost to Respondent

The cost to the applicant for completing the application is based on the average hourly wage for an NIH entry-level tenure-track scientist (\$39.46 per hour). Typically, recommenders 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, thus the cost for recommenders to complete the recommendation form is based on an average hourly rate of \$56.49. The cost to the institutional business officer is based on the median annual salary for a bachelor’s level bursar, which is \$63,581, which sets the estimated wage at \$30.45 per hour. LRP Coordinators are typically NIH employees at the GS 13 level, so the cost to the coordinator is based on the hourly rate of a Grade 13, Step 5 (\$52.66 per hour). A projection of these estimates is shown in Table 12-2.

Table 12-2 Annualized Cost to Respondents

Type of Respondents	Total Annual Burden Hours	Hourly Respondent Wage Rate	Respondent Cost
Applicants*	21,840	\$39.46	\$861,806.40
Recommenders*	5,380	\$56.49	\$303,916.20
Institutional Business Officers**	221	\$30.45	\$6,729.45
NIH LRP Coordinators***	40	\$52.66	\$2,106.40
TOTAL	27,481		\$1,174,558.45

*Bureau of Labor Statistics: The General Public rate was obtained from the <https://www.bls.gov/ooh/life-physical-and-social-science/medical-scientists.htm>.

** The Chronicle of Higher Education: The bachelor’s level bursar rate was obtained from <http://www.chronicle.com/article/Median-Salaries-of-Senior/235668>.

*** Office of Personnel Management: The 2019 General Schedule (GS) Locality Pay Table was obtained from https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/DCB_h.pdf.

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

There are no additional costs associated with this information collection.

A.14 Annualized Cost to the Federal Government

The annualized cost to the Federal Government for administering the LRPs is expected to be \$1,720,394 which includes \$1,020,173 for the continuing development and maintenance of the LRP Management Information System and Online Application System (LRP Central) and \$700,221 for staff and contractor salaries. The Division of Loan Repayment will provide ongoing administrative support for all loan repayment programs. This includes application receipt/support and the eligibility and financial reviews. This work by the DLR will require a portion of the time from the following staff and contractors:

Cost Descriptions	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Director	15/4	148,267	5%		\$ 7,413
Director of Operations	15/10	164,200	10%		16,420
Program Analyst	14/10	148,967	25%		37,242
Program Analyst	13/6	113,132	25%		28,283
Program Analyst	9/5	63,732	25%		15,933
Financial Analyst	12/7	97,858	30%		29,357
Support Specialist	8/10	66,191	30%		19,857
Contractor Cost					\$ 1,020,173
Total					\$ 1,720,394

* the Salary in table above is cited from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/18Tables/html/DCB.aspx>

A.15 Explanation for Program Changes or Adjustments

There were adjustments made to the instruments. In 2017, NIH requested changes to this information collection to improve the user's experience and reduce instances of user error. For example, we adopted the use of electronic signatures on the Certifications for Online Applications form (NIH 2674-9) and the NIH Loan Repayment Program Contract (NIH 2674-12), which improved the user's experience. We also made changes that reduced instances of user error, such as moving the list of Eligibility questions (NIH 2674-20) to the end of the online application to allow users to review their answers prior to submitting the application, and added Confirm Email field to the Applicant Information form (NIH 2674-1), which reduced instances of user error (e.g., typos in email address). In 2018, NIH requested changes to this information collection by moving the Mentor Biosketch form (NIH 2674-13) to provide a single destination for Applicants to upload documents. Additionally, we improved the process of identifying applicants' research supervisors and primary mentors by including their organization and position title on the Colleague Information section of the Applicant Information form (NIH 2674-1). In 2019, a change request was approved to add an optional question the list of Eligibility questions (NIH 2674-20) regarding an applicant's status as an individual from a health disparity population to ensure that no fewer than 50 percent of the Health Disparities Research LRP contracts are for members of a health disparity population. Due to the changes made in 2017 and 2018, applicants are expected to

spend approximately 8 hours to complete and assemble their information for the application, a decrease from 10-11 hours in 2016. As a result, the total burden hours are estimated at 27,481 hours, a decrease of 5,761 burden hours since 2016.

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

The data gathering 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, included in the online LRP Data Dashboard, and/or used for periodic evaluation studies of program effectiveness.

The anticipated schedule for the annual NIH LRP application cycle is listed below:

A.16 - 1 Project Time Schedule	
Activity	Time Schedule
LRP Application Period	September 1 to November 15
Application Peer Review	February to May
Initial Selection	May
Financial Vetting	May to July
Final Funding Decisions and Recipient Notification	July
Contract Signing	August-September
First Loan Repayment to Lender	October

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

The OMB control number will be displayed (currently expires 8/31/2019).

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

None