

**Supporting Statement A for
International Research Fellowship Award Program
of the National Institute on Drug Abuse
OMB # 0925-0733, exp., date 2/28/2019**

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Attachments

1. Attachment 1- Form - Application for International Research Fellowship Award Program
2. Attachment 2 – Form –Mentor Information and Agreement Form
3. Attachment 3 - PIA Form
4. Attachment 4 - NIH Privacy Act Officer Memo

Abstract.

The 2015 approval covered an application form for a postdoctoral and professional development program initially developed in partnership with the International AIDS Society (IAS) focused singularly on HIV and drug use. That program attracted exceptionally qualified applicants, and the individuals who received the fellowships continue to make significant contributions to field of addiction research. The partnership with IAS did not permit NIH/NIDA to require that mentors be NIH/NIDA-supported grantees, however, and that requirement became increasingly important to NIH/NIDA to ensure that every application would address U.S. and, more specifically, NIH/NIDA research priorities.

A1. Circumstances Making the Collection of Information Necessary

The National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH), requests a three-year clearance for the application form that the Institute will use for its International Postdoctoral Research Fellowship Award Program. This program will recruit postdoctoral researchers into a fellowship research training program for drug use, abuse, addiction, and drug-related consequences. The program will train new investigators to conduct research in any aspect of drug use, from social science to basic science, including epidemiology, prevention, treatment, and preclinical and clinical sciences, to advance addiction science while fostering multinational research in this disease area. The program is open to all foreign nationals.

The legal authority granted to NIH to train future biomedical scientists comes from several sources. Title 42 of the U.S. Code, Sections 241 and 282(b)(13) 282 (11)B authorize the Director, NIH, to conduct and support research training for which fellowship support is not provided under Part 487 of the Public Health Service (PHS) Act (i.e., National Research Service Awards), and that is not residency training of physicians or other health professionals. Sections 405(b)(1)(C) of the PHS Act and 42 U.S.C. Sections 284(b)(1)(C)] and 285-287 grant this same authority to the Director of each of the Institutes/Centers at

NIH. NIDA considered the need to increase research training for the treatment and prevention of drug use, abuse, addiction, and drug-related consequences. Clearance for the application form for this training program is needed.

A2. Purpose and Use of the Information Collection

The purpose of the proposed information is for the selection of the best applicants for this fellowship program. An application form to obtain information about the potential of fellows for successful training in addiction research is necessary. NIDA will request clearance for any additional forms that may be needed if programs or components are added to this program in the future, or if the form for this program needs some modifications for better clarity of information.

The information ensures that fellows applying to these programs meet eligibility requirements; indicates their potential as future scientists; determines where mutual research interests exist; and enables decision-making regarding which applicants will be proposed and approved for fellowship awards. In each case, completing an application is voluntary, but in order to receive due consideration, the prospective applicant must complete all fields required by the program.

The program has evolved to one funded solely by NIH/NIDA to provide postdoctoral research training and professional development activities for foreign nationals investigating any aspect of drug use, abuse, addiction, or drug-related consequences. Mentors must be currently funded by NIH/NIDA and work at a U.S. institution.

The separate “Applicant Consent Form” in the 2015 application was created to ensure that fellows working with non-U.S. mentors would comply with NIH/NIDA regulations. Because mentors must be currently funded NIH/NIDA grantees, these ethical conduct of research assurances are confirmed during the NIH/NIDA grant application and award process. The separate form is eliminated in this revised submission and replaced with applicant and mentor certification and assurance language has been incorporated directly into the application itself.

This reduces the amount of paperwork required while ensuring that the applicants and mentors accept their responsibilities to follow the regulations.

This revised application submitted for OMB review reflects the current web-based application and program requirements, including expanding the research topics to be investigated, limiting mentors to NIH/NIDA grantees at U.S. institutions, and incorporating the assurance of ethical research conduct.

Details of the Program are as follows:

This program will offer awards annually to junior scientists for postdoctoral training, with a NIDA-funded grantee at a U.S. institution.

Identification of participants to matriculate into the program comes from the application form and the form will be hosted at the NIDA Web site <http://www.drugabuse.gov/> upon receiving OMB clearance. The proposed information collection activity is necessary in order to determine the eligibility and quality of potential awardees for the research training opportunity of this program. The form for this program was developed by NIDA staff, Steve Gust and Stuart Berlin.

Prospective trainees for the fellowship opportunity must apply directly to the NIH/NIDA using the application form. Participation in this program is restricted to non-U.S. citizens, and the principal appointment authority for this program comes from the Authority mentioned above.

The awards of this program will be made annually. The application form may be renewed annually through an internal process for changes that may be needed and to prevent any duplication of information. The financial support provided to the awardees comes from NIDA.

Application Guidelines: The guidelines for this Program will be available on the NIDA website <http://www.drugabuse.gov/> upon obtaining OMB clearance and no later than April 2019. The Guidelines will comply with the Plain Writing Act of 2010, to provide clear

communication that the public can understand and use. For future guidelines and changes the Federal Plain Language Guidelines will be followed similarly.

For this program contact information and research experience history is also asked of the proposed mentor.

The NIDA science programs staff review the applications, determine the applicants who are eligible for the awards, and process the information to be sent to the applicants.

The information may also be used by NIDA for strategic planning, performance analysis, and to provide information to the Administration and the Congress if needed, on the overall program.

A3. Use of Information Technology and Burden Reduction

The applications will be Web-based and will be made accessible through the NIDA site at <http://www.drugabuse.gov/>. A Privacy Impact Assessment (PIA) is pending, see attachment 3. The information requested is for the purpose of identifying applicants with the best and most needed research that would be productive from training for research on addiction, the best capacity for research training, and strong interests in a biomedical research career.

Features of the online applications include, but are not limited to the following elements:

- Edit submitted application to ensure up-to-date information for evaluation
- E-mail confirmation of start of an application
- E-mail confirmation of successful submission of application,
- Request for resubmission of recommendations and/or other information via e-mail program
- E-mail notification of application status

In addition, prospective applicants will be able to review Web pages hosting Application, Instructions, and Program Policies and Procedures prior to submitting an application for admission consideration. The details to be posted on the site will enable applicants to carefully complete and submit a well-organized application. The estimated time to complete an application of this program is 60 minutes, based on the similarity of the information and number of items asked by the US PHS-398 grant application form.

The NIDA online system reduces the burden on every applicant by streamlining the application process, improves agency efficiency and responsiveness to the public, and reduces the financial cost to applicants (there is no application fee for these programs), and the online application process eliminates the cost of shipping applications internationally.

A4. Efforts to Identify Duplication and Use of Similar Information

Applicants to the program must submit an application through the NIDA system because there are no duplicate sources available for the information needed.

A5. Impact on Small Businesses or Other Small Entities

No small business or other small entities will be affected by this program. Some applicants for the program may be affiliated with small, nonprofit organizations or may be independent clinicians. Every effort has been made to streamline processes and instructions and to simplify the application and reporting processes. The Institute's internal clearance process ensures that no undue burden is placed on any applicant for these kinds of research training programs.

A6. Consequences of Collecting the Information Less Frequently

This program will be implemented annually in the sense that each year a new set of participants is selected and funded. The information is collected only once for an award. It cannot be collected less frequently.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This information collection is consistent with these guidelines. Submitting an application to this program is voluntary.

A8. Comments in Response to Federal Register Notice and Efforts to Consult Outside Agency

Notification of information collection for the Training Programs was published on December 14, 2018, in the Federal Register Notice, #2018-27107, 83 FR64348, (pp 64348-49). During the 60-day notice period, no comments were received.

Dr. Steve Gust developed the application form for this program, with support from Stuart Berlin of the NIDA Information Resource Management Branch.

A9. Explanation of Any Payment or Gift to Respondents

No payments or gifts are provided to respondents for completing an application form.

A10. Assurance of Confidentiality Provided to Respondents

The information collected is available to NIH staff via an internal SharePoint site. The staff includes science and program officials who recommend or approve awards, administrative staff, human resources staff, financial officials who prepare the necessary documentation to arrange for stipend payments and to activate, renew, or terminate approved awards. Access to the applications will be via protected login credentials. Privacy is assured to the extent provided by law. Applicants will be able to access the application site via a link and will enter their information after establishing login credentials that include "strong" passwords that conform to standards used by the NIH Center for Information Technology. Applicants will have access to only their own applications once they have been uploaded to the site. Letters of recommendation that may be submitted to NIDA will be stored in the protected NIH/NIDA protected servers with restricted access.

The information is collected and maintained in accordance with the DHHS Automated Information Systems Security Program Handbook. For all applications the software used is on

an internal shared NIH server residing inside the NIH firewall. The NIH Privacy Act Office has determined that the Privacy Act will apply to this information collection. (See Attachment 4).

A11. Justification for Sensitive Questions

No sensitive information on sexual orientation, risk behaviors, religious beliefs, or other personal matters is asked.

A12.1 Estimated Annualized Burden Hours

The estimated time to complete the online application is 60 minutes, based on its length and information items that are similar to the PHS-398 grant application form that has OMB clearance. The estimated time to complete the mentor agreement form is 20 minutes. The expected number of applicants for this program is 45, the expected number of applicants signing the consent form is 45, the expected number of mentors for this program is 45, the total expected number of respondents is 90.

Table A12-1. Estimated Annualized Burden Hours

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Annual Burden Hours
A. Application	Applicant Scientists	45	1	1	45
B. Mentor Information and Agreement	Scientists	45	1	20/60	15
	Totals	90	90		60

A. 12.2 Annualized Cost to Respondents

There are no costs to respondents other than their time to complete the forms. The costs to respondents for this time is in Table A12.2 below.

Table 12-2 Annualized Cost to Respondents

Type of Respondent	Total Annual Burden Hours	Hourly Respondent Wage Rate *	Respondent Cost
Applicant Scientists	60	\$39.46	\$2367.60
TOTAL	60		\$2367.60

* Mean hourly wage estimates (calculated with data collected from employers in all industry sectors in metropolitan and nonmetropolitan areas in every state and the District of Columbia) for Healthcare Practitioners and Technical Occupations as available from the Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook*, Medical Scientists, on the Internet. Retrieved from <http://www.bls.gov/ooh/life-physical-and-social-science/medical-scientists.htm> on 11/07/2018.

A13. Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital costs, operating costs, or maintenance costs to report.

A14. Annualized Cost to the Federal Government

The cost to the Federal Government of this program is approximately \$308,100 a year. The time of the NIDA Program Official for this program is five percent at a cost of \$5,600, and the Contractor cost is \$2,500. The total annual cost to the Federal Government is approximately \$316,200.00.

Table A.14. Annualized Cost to the Federal Government

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight – Program Analyst	13/10	\$112,000	5		\$5,600

Contractor Cost		\$50,000	5		\$2,500
Program Fellowships and Awards					\$308,100
Travel					
Other Cost					
Total					\$316,200

A15. Explanation for Program Changes or Adjustments

This is a renewal information collection request, with changes due to programmatic adjustments to the fellowship training program, and due to including assurance language for the ethical conduct of research within the application form itself in order to discontinue the Applicant Consent form initially used for this purpose. This program was initially developed in partnership with the International AIDS Society (IAS) focused singularly on HIV and drug use. The program attracted exceptionally qualified applicants, and the individuals who received the fellowships continue to make significant contributions to field of addiction research. The partnership with IAS did not permit NIH/NIDA to require that mentors be NIH/NIDA-supported grantees, however, and this requirement that mentors be NIH/NIDA-supported grantees became increasingly important to NIH/NIDA to ensure that every application would address U.S. and, more specifically, NIH/NIDA research priorities. The program has evolved to one funded solely by NIH/NIDA to provide postdoctoral research training and professional development activities for foreign nationals investigating any aspect of drug use, abuse, addiction, or drug-related consequences. The separate “Applicant Consent Form” in the 2015 application was created to ensure that fellows working with non-U.S. mentors would comply with NIH/NIDA regulations. Because mentors must be currently funded NIH/NIDA grantees, these ethical conduct of research assurances are confirmed during the NIH/NIDA grant application and award process. The separate form is eliminated in this revised submission and has been replaced with applicant and mentor certification and assurance language incorporated directly in the application itself. This reduces the amount of paperwork required while ensuring that the applicants and mentors accept their responsibilities to follow the regulations.

This revised application submitted for OMB review reflects the current web-based application and program requirements, including expanding the research topics to be investigated, limiting mentors to NIH/NIDA grantees at U.S. institutions, and incorporating the assurance of ethical research conduct within the application itself thereby decreasing the number of forms to be completed.

A16. Plans for Tabulation and Publication and Project Time Schedule

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

Activity	Time Schedule
Program Applicant Recruitment	Ongoing May through March annually with renewal
Participant Enrollment and Data Collection (annually)	–March -July
Data Management and Analysis (annually)	Ongoing through December

A17. Reason(s) Display of OMB Expiration Date Is Inappropriate

The OMB control number and expiration date will be displayed.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the Certification for Paperwork Reduction Act Submissions.