APPLICATION FOR THE

PHARMACOLOGY RESEARCH ASSOCIATE PROGRAM

OMB No. 0925-0378

SUPPORTING STATEMENT

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A. Justification

A.1. Circumstances Making the Collection of Information Necessary

This is a request for approval of forms used by individuals applying for the Pharmacology Research Associate (PRAT) Program. The PRAT Program, authorized by 42 USC 209(g) and 42 CFR Part 61B, Public Health Service Regulation and Section 301 of the Public Health Service Act offers opportunities for training and experience in laboratory or clinical investigation to individuals with a Ph.D. degree in pharmacology or a related science, M.D., or other appropriate professional degree through appointments as PRAT Fellows at the National Institutes of Health (NIH) or the Food and Drug Administration (FDA). The appointments are based on knowledge, training, and/or research experience. The selection of candidates is highly competitive, with preference given to applicants with outstanding academic records and references, and who show the greatest potential to become leaders in the field of pharmacology. With up to seven available slots per year and approximately 30 applicants, these two forms will provide academic and scientific credentials as well as evaluations provided by references, to be used in the selection process. Only essential information with a minimum burden to the respondent is requested.

Profiles of graduates of the PRAT Program demonstrate its continued success in providing leaders in pharmacological research for academia, industry, and government laboratories. Since the selection of candidates is based on the review of

the application and evaluation forms, the continuing strength of the program relies heavily on the respondent information provided on the forms to ensure that the most qualified applicants are identified. This information is used only at the time of review.

Potential applicants will be informed about the PRAT Program through web based transmissions of the Pharmacology Research Associate Program **(Attachment 1)**, as well as the PRAT Program fact sheet **(Attachment 2)** which will be distributed to various sources such as graduate programs, and medical, dental, and pharmacy schools. In addition, the PRAT Program fact sheet is distributed at national scientific meetings, e.g., the annual meetings of Experimental Biology, American Association of Cancer Research (AACR), Neuroscience, Cell Biology, and the annual research forum for NIH postdoctoral fellows. Information on the PRAT Program is also mentioned in the newsletters of different scientific societies, e.g., AACR, American Society for Pharmacology and Experimental Therapeutics (ASPET) and the American Society for Biochemistry and Molecular Biology (ASBMB). It is also mentioned in the NIH Catalyst and/or the NIH Record. The PRAT Program's application package is accompanied by an applicant introductory letter **(Attachment 3)** from the Co-Directors of the PRAT Program. The letter provides instructions on how to properly complete the application package. Enclosures to the applicant introductory letter include the NIH 2721-1 application form **(Attachment 4)**, the NIH 2721-2 evaluation form **(Attachment 5)**, and an evaluator cover letter from the Co-Directors of the PRAT Program, notifying each evaluator

why the information is being sought, requesting each evaluator's cooperation in completing the NIH 2721-2 evaluation form, and providing brief instructions on how to appropriately do so. **(Attachment 6).**

Only U.S. citizens or permanent residents of the United States who have been awarded a terminal degree, or who have been certified by a university as meeting all the requirements leading to a doctorate may be hired as PRAT Fellows. These positions are excepted positions in the civil service and are administratively located within the National Institute of General Medical Sciences (NIGMS), and the site of work is at one of the intramural laboratories of the National Institutes of Health (NIH) or the Food and Drug Administration (FDA). When the employee enters on duty he/she becomes an NIH Intramural Research Training Award (IRTA) Fellow [non-Full Time Equivalent (FTE)] for his/her first year, and then enters a non-tenured government employee status under the Service Fellow Authorization previously mentioned, for the remaining two years of the three year program. **(42 USC 282(b)(13), 42 USC 209(g) and 42 CFR Part 61B, Public Health Service Regulation)**.

The application for the PRAT Program requests only information that is unique to the program and which is essential for the complete evaluation of applicants. The PRAT Program's application and evaluation forms consist of the following:

1. The NIH 2721-1 application form to the PRAT Program requests the following information from the applicant: contact information; summary of education, and professional/clinical training; scientific honors/awards received; requested preceptor;

previous research experience; publications s/he has written; what special training they wish to obtain from this program, what his/her career goals are; what his/her research plans are; how the research and training proposed advances the field of pharmacology; references; their citizenship; and how they heard of the PRAT Program.

a. The PRAT Applicant Introductory Letter provides respondents detailed supplemental instructions concerning questions 14 and 15 on the NIH 2721-1 application form **(pp. 4-5, Attachment 4)**. Requested information such as providing a research plan, and providing information about how participation in the PRAT Program will contribute to or advance the field of pharmacology is essential to selecting the most highly qualified applicants. Additionally, a question inquiring how a respondent has learned of the PRAT Program ensures that future mailings of the Program's information packet, and fact sheet will reach intended target audiences.

2. The NIH 2721-2 evaluation form requests that references provide information on the applicant's potential in the field of research. This includes providing information concerning the applicant's academic and research performance, his/her interpersonal skills as they relate to a research career, and an assessment of the applicant's potential to become a contributing investigator in the pharmacological sciences.

3. The "Biographical Sketch" of the Preceptor Selection Verification Form **(Attachment 7)** offers applicants and preceptors a format for documenting their education/training, as well as their research and professional experience. Applicants and preceptors are encouraged to complete the "Biographical Sketch" attachment (not to exceed two pages) in lieu of submitting a curriculum vitae. (Past submissions

have shown that applicants and preceptors frequently submitted curriculum vitaes exceeding two pages).

A.2. **Purpose and Use of the Information**

The collected information is used for the one-time purpose of reviewing and selecting applicants for the PRAT Program. The information will be evaluated for scientific merit and for training potential. This process is accomplished by an ad hoc committee of distinguished senior scientists selected from both the intramural NIH programs, the FDA, and nationally recognized extramural research laboratories who have knowledge of the PRAT Program and its goals. Selection is made on a highly competitive basis, with preference given to applicants with outstanding potential to become scientific leaders in the field of pharmacology. Considerations include: intellectual attainment, demonstrated research interest, and research accomplishments. Applicants are also requested to complete a "Preceptor Selection Verification Form," **(Attachment 7)** which documents that the preceptor has intended to sponsor the PRAT Fellow, if he/she is accepted into the PRAT Program, and that suitable laboratory space, resources, and guidance will be provided. The credentials of the preceptor will also be considered, as well as the value of the training experience for the PRAT Fellow, and the significance to the field of pharmacology. After this screening of applications, reference checks are conducted on selected candidates.

The information collected has been found to be highly accurate, adequate, and reliable because it is prepared by the principal parties, namely the fellows and the preceptors. Moreover, the collected information is used by the PRAT Program office fairly promptly (within eight weeks) after it is received. Only information that is unique to the PRAT

Program and is absolutely necessary for the complete evaluation of applicants for the program is requested. The data have been used to assess the applicant's scientific knowledge and research training abilities. Information such as the applicant's career and research plans, as well as his/her academic objectives are critical evaluation factors. Not having this information would seriously undermine the PRAT Program's ability to offer training and research opportunities to individuals capable of being future leaders in the field of pharmacological research.

Over the last three years, the PRAT program application process has run effectively.

A.3. **Use of Information Technology and Burden Reduction**

The PRAT Program office will use electronic transmission to send information about the PRAT Program and application packets to make use of information technologies. In the past, this information was sent as standard mailings through the US Post Office to approximately 1000 graduate programs, medical, dental and pharmacy schools to notify graduate advisors and students of the program. If information cannot be received or submitted electronically by potential applicants, paper copies will be accepted which are submitted by mail or fax transmission.

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

The information is not collected in connection with any other programs and is not available from any other source.

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

To be eligible for the PRAT Program, candidates must be U.S. citizens or permanent residents of the United States who have been awarded a doctoral degree, or who have been certified by a university as meeting all of the requirements leading to a

doctorate. Thus, physicians (who may be considered "small businesses") may be included as possible respondents; however, the number of burden hours is kept to a minimum.

A.6. Consequences of Collecting the Information Less Frequently

The information is collected only once in any given year, when an individual applies to the program. The target population for this program are young scientists just entering their postdoctoral research careers, thus the pool changes on a yearly basis as more people enter it and others find positions at other institutions. Applications received are kept for one year and those candidates who are not selected for the PRAT Program can request to have their individual initial application reactivated for consideration in the subsequent request for applicants, as long as the applicant who is requesting that his/her application be reactivated for reconsideration, is not employed with HHS for more than a year, at the time of re-submission. Although the same initial application can be reactivated for the subsequent request for candidates for the PRAT Program, each applicant is encouraged to update the information on his/her application form.

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

This information collection complies with the guidelines of 5 CFR 1320.5.

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

Feedback from informal interactions and consultations with past applicants has not elicited any concerns about the application form itself. The information collection appears to be well-received. The 60-day Federal Register notice was published May

18, 2010, pages 27789-27790. One comment was received on 6/25/2010. The public respondent requested that eligibility for this program be offered to American Citizens only. As stated in A.1., Justification, of this Supporting Statement A, applicants for this program must be U.S. Citizens or permanent residents of the United States who have been awarded a terminal degree, or who have been certified by a university as meeting all the requirements leading to a doctorate may be hired as PRAT Fellows.

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

Payment or gifts are not provided to respondents for this information collection.

A.10. Assurance of Confidentiality Provided to Respondents

The application and evaluation forms are in accordance with the provisions of the Privacy Act. All records are maintained on a secured computer, and all paper forms are stored in a locking file cabinet; as stated in Systems Number 09-25-0124 of the "Systems of Records Notice" **(Attachment 8)**. The statement on the "Request for Evaluation of Applicant" **(Attachment 5)** indicating that the form is NOT CONFIDENTIAL is needed to indicate to the evaluator that his/her comments may be reviewed by the applicant and/or any Federal government employee who may require this information to evaluate a candidate or process the paperwork to begin the employment process. Under the Privacy Act of 1974 the applicant may also have access to the information contained on this form.

The original file of the completed and executed application will be retained by the PRAT Program office. Authorized users of this information are employees who maintain the system, and are instructed to grant access only to authorized personnel

(System Manager and staff assigned to the program). Physical safeguards include maintaining the records on computers of the PRAT assistant and codirectors with confidential passwords and maintaining paper copies of application material in locked file cabinets during non-working hours. In addition, procedural safeguards include restricting access to files to responsible individuals who have been instructed in the Privacy Act requirements. We certify that the information collected complies with the Privacy Act of 1974 and OMB Circular A-108. "Responsibility for the Maintenance of Records about Individuals by Federal Agencies." Systems Number 09-25-0124, "Administration: Pharmacology Research Associates, HHS/NIH/NIGMS." Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1--"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 2300-320-2(a).

Each candidate's qualifications are carefully reviewed by the PRAT Selections Committee, which consists of distinguished senior scientists selected from both the intramural NIH programs, the FDA, and nationally recognized extramural research laboratories who have knowledge of the PRAT Program and its goals. A notice in the PRAT Program's application package (which includes the NIH 2721-1 applicant form and the NIH 2721-2 evaluation form) aptly informs candidates of the confidentiality of the information they provide. **(Attachments 4 and 5)** In brief, the information that is supplied by both the candidate and the referees will not be disclosed, without the candidate's prior written consent, to anyone who is not an employee of the Department of Health and Human Services, except as provided by law. In addition, this

same notice informs the candidate of the applicability of the Privacy Act and its implications. **(Attachment 9)**

A.11. **Justification for Sensitive Questions**

Only information that is relative to the individual's ability to perform as a PRAT Fellow is requested. In the past, a social security number was requested as part of the application process, but this has now been eliminated from the present application form. A social security number will be requested from those individuals who are invited into the program to complete employment forms and initiate the hiring process.

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

Approximately 25 persons per year apply for the PRAT program. The estimated burden hours incurred by applicants (respondents) is approximately 8 hours to apply. The estimated burden hours incurred by referees (respondents) is approximately 105 minutes to apply.

A.12 - 1 Estimates of Hour Burden:

Type and Number of Respondents	**Responses Per Respondent**	**Total Responses**	**Hours**	**Total Hours**
Applicants 25	1	25	8.00	200.0
Referees 75	1	75	1.75	131.25

Total Number of Respondents 100
Total Number of Responses 100
Total Hours 331.25

A.12-2 Annualized Cost to Respondents:

Applicants: 200 hours x $50.00/hour = $10,000.00

25 applications x $10.00/transcript costs = $ 250.00

TOTAL = $10,250.00

Referees: 157.5 hours x $50.00/hour = $ 6,562.50

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

No other annual cost burden to respondents or recordkeepers exist.

A.14. Annualized Cost to the Federal Government

This activity is an ongoing collection of information.

Annualized Cost to the Federal Government:

Mailing (forms, applications)	$ 50.00
Printing	$ 100.00
Staff Time	$ 30,000.00
Any other costs: artwork; supplies	$ 500.00
Total	$ 30,650.00

A.15. Explanation for Program Changes or Adjustments

There are no known program changes or adjustments to this information collection.

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

Applications are reviewed 6 months prior to the PRAT Fellow's proposed appointment date. Fellows are to serve a 3-year non-renewable appointment. An applicant is notified by telephone and in writing should he/she be selected into the PRAT Program. There are no plans for statistical analyses in publications for this information collection.

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

As required, the OMB expiration date shall be printed in the upper right-hand corner of the documents supporting this information collection.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

This information collection adheres to the provisions of the Certification Requirements for Paperwork Reduction Act Submissions.

B. Collections of Information Employing Statistical Methods

This information collection does not employ statistical methods