

Supporting Statement A for

Individual Ruth L. Kirschstein National Research Service Award
Applications and Related Forms (OD)

July 24, 2008

Name: Pam Gilden
Address: Division of Grants Policy
Office of Policy for Extramural Research Administration
6705 Rockledge Drive, RKL1, Suite 350
Bethesda, MD 20892-7974
Telephone: 301-594-6739
Fax: 301-435-3059
Email: gildenp@mail.nih.gov

**Individual Ruth L. Kirschstein National Research Service Award Applications
and Related Forms**

OMB Approval Number: 0925-0002

Supporting Statement

Table of Contents.....2

List of Attachments.....4

OVERVIEW.....5

A. Justification.....6

A.1 Circumstances Making the Collection of Information Necessary.....6

A.2 Purpose and Use of the Information Collection.....8

A.3 Use of Information Technology and Burden Reduction.....10

A.4 Efforts to Identify Duplication and Use of Similar Information.....14

A.5 Impact on Small Businesses or Other Small Entities.....14

A.6 Consequences of Collecting the Information Less Frequently.....15

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.....15

A.8 Comments in Response to the Federal Register Notice and Efforts to
Consult Outside Agency.....15

A.9 Explanation of Any Payment or Gift to Respondents.....15

A.10 Assurance of Confidentiality Provided to Respondents.....15

A.11 Justification for Sensitive Question.....16

A.12 Estimates of Hour Burden Including Annualized Hourly Costs.....16

A.13 Estimates of Other Total Annual Cost Burden to Respondents or Record
Keepers.....18

A.14 Annualized Cost to the Federal Government.....18

A.15 Explanation for Program Changes or Adjustments.....19

A.16 Plans for Tabulation and Publication and Project Time Schedule.....19

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate.....19

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions.....19

LIST OF ATTACHMENTS

Data Collection Instruments:

Attachment 1 – PHS 416-1 Ruth L. Kirschstein NRSA Individual Fellowship Application

Attachment 2 – PHS 416-9 Ruth L. Kirschstein NRSA Individual Fellowship Progress Report

Attachment 3 – PHS 416-5 Activation Notice

Attachment 4 – PHS 416-7 Termination Notice

Attachment 5 – PHS 6031 Payback Agreement

Attachment 6 – PHS 6031-1 Annual Payback Activities Certification (APAC)

Instructions:

Attachment 7 – PHS 416-1 Ruth L. Kirschstein NRSA Individual Fellowship Application

Attachment 8 – PHS 416-9 Ruth L. Kirschstein NRSA Individual Fellowship Progress Report

Attachment 9 – 416 Component Forms

Attachment 10 – Summary Table of Significant Changes

Attachment 11 – Privacy Act: [09-25-0036](#), Extramural Awards and Chartered Advisory Committees (IMPAC 2), Contract Information (DCIS), and Cooperative Agreement Information, HHS/NIH

Attachment 12 – CFDA List

Overview

The Congress of the United States established the Ruth L. Kirschstein National Research Service Award (NRSA) Program in 1974 to "increase the capability of the Institutes of the National Institutes of Health (NIH) to carry out their responsibility of maintaining a superior national program of research into the physical and mental diseases and impairments of man." Congress extended the authority to make Kirschstein-NRSAs to the Agency for Healthcare Research and Quality (AHRQ) in 1985. The Congress felt that the success of the Federal research effort depended on the availability of excellent scientists. One of the mechanisms established to ensure this goal was direct training support through individual Kirschstein-NRSAs.

The Public Health Service Grant Application PHS 416-1, Ruth L. Kirschstein National Research Service Award Individual Fellowship Application, is used by these applicants to request federal assistance for research-related training. For purposes of this collection, we are referring only to the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ). Also included under the 0925-0002 control number are the following:

- The PHS 416-9, Individual Fellowship Progress Report for Continuation Support, used in determining continuation of support during the period of award.
- The PHS 416-5, Activation Notice, used by individuals to indicate the start date of their award.
- The PHS 416-7, Termination Notice, used by awardees and trainees when support ends. Also the information establishes each individual's payback obligation where applicable.

- The PHS 6031, Payback Agreement, used by individuals at the time of activation to certify agreement to fulfill the payback provisions.
- The PHS 6031-1, Annual Payback Activities Certification, used by individuals to show whether payback service has been engaged in and by PHS to administer the legislated payback requirements of the NRSA program.

A. Justification

A.1 Circumstances Making the Collection of Information Necessary

The Application for Public Health Service Individual Ruth L. Kirschstein National Research Service Award (Kirschstein-NRSA), PHS 416-1 (Attachments 1, 7, and 9), is necessary to enable individuals to request funds from the NIH and AHRQ. The form is required at various times and circumstances in the course of activities proposed to be carried out under the range of authorized PHS programs: initial or original requests; competing continuation requests for extension beyond the previously approved award period; supplemental requests for additional funds beyond those approved and awarded for an annual budget period.

The Individual Ruth L. Kirschstein National Research Service Award Progress Report for Continuation Support, PHS 416-9 (Attachments 2 and 8), is used by the Public Health Service for noncompeting continuation support. Funds for subsequent budget periods within an approved project period must be requested in an annual continuation progress report. The level of funding for the ensuing budget period will be determined from review by Institute and Center staff of the progress report within the framework of the previously approved fellowship grant and the recommended level of support, the progress reported, and the availability of funds.

Multiple uses of the PHS 416-1 and PHS 416-9: These applications are used for all types of Kirschstein-NRSA Individual Fellowships—Predoctoral, Postdoctoral, and Senior. Special instructions may apply to Predoctoral and Senior Fellowship Applicants. In addition to the Predoctoral and Postdoctoral Individual Kirschstein-NRSA, the PHS uses these applications for other programs including the following: Individual Predoctoral Kirschstein-NRSA for M.D./Ph.D. Fellowships; Kirschstein-NRSAs for Senior Fellows; MARC Kirschstein-NRSA Faculty Fellowships, Intramural Individual Postdoctoral Program Appointee; MARC Visiting Scientists Fellowships; Postdoctoral Medical Informatics Fellowships and Senior Medical Informatics Fellowships.

PHS 416-5, Activation Notice (Attachment 3), is used by individuals to indicate the start date of their awards. Individuals have a 6-month period after the initial award is issued to begin training.

PHS 416-7, Termination Notice (Attachment 4), is used by awardees and trainees when supports ends. Also the information establishes each individual's payback obligation where applicable.

PHS 6031, Payback Agreement (Attachment 5), is completed when an individual activates certifying agreement to fulfill the payback provisions. Certain National Research Service Awardees are obligated to payback in service or dollars based on the length and amount of support. This payback is required by legislation under the National Research Act of 1974 (42 USC 288).

PHS 6031-1, Annual Payback Activities Certification (Attachment 6), is completed by individuals to show whether payback service has been engaged in and whether such service is acceptable.

The Individual Ruth L. Kirschstein National Research Service Awards were established under statutory authorities contained in the PHS Act, as amended (42 USC 288). The awards are authorized in accordance with 42 USC 288.

Information collection requirements specified in the regulations governing the Public Health Service NRSA program, including 42 CFR 66.104 (b) (application requirement), 42 CFR 66.105 (b) (candidate assurance and certification) and 42 CFR 66.110 (service, payback, and recovery requirements).

This information collection is currently approved under OMB 0925-0002 (Expiration 10/31/08).

A.2 Purpose and use of the Information

The PHS 416-1 is used by Federal agency staff and Public Advisory Committees and National Advisory Boards and Councils as a basis for evaluating applications in light of agency initiatives and programmatic goals in order to carry out the Agency missions in a highly competitive fiscal environment. The information on the PHS 416-9 is used for program management, planning, budgeting, and appraisal of progress. Both of these forms are used for reporting to Congress and to the public.

PHS 416-1 – The basic application which comprises the majority of the respondent burden, is used by applicants, staff and consultants of NIH and AHRQ as follows:

- a) by applicants to compete for funding for research training activities and to request access to agency resources;
- b) by the Center for Scientific Review, to determine the basic eligibility of the individual for an award, and to assign the application to the appropriate scientific review group (SRG) and PHS awarding component.
- c) by the SRGs to determine the scientific merit of the application and to identify those most likely to develop into independent investigators. It is for this purpose that the bulk of the information is requested;
- d) by PHS to obtain data on the candidate for processing purposes and later as a data base for program management and analysis;

e) by the PHS awarding components to select awardees, to determine the fiscal benefits under the award, and to administer the award in compliance with the legislation, regulations and program policies.

f) the assurance checklist part of the PHS 416-1 and PHS 416-9 is used to ensure that individuals and sponsoring institutions comply with applicable requirements of Federal law and regulations.

PHS 416-9 - The Progress Report for Continuation Support is used by the PHS awarding component to ascertain the progress made under the award, the plans for the next year, and compliance with applicable policies and procedures.

PHS 416-5 - The Activation Notice is used by individuals to indicate the start date of their awards. Individuals have a 6-month period after the initial award is issued to begin training. Also the data is used to determine the timing of subsequent actions such as the notification of the progress report by which the individual applies for support for each additional year. The information is used by the PHS awarding component to establish the start date in the record.

PHS 416-7 - The Termination Notice is submitted to the PHS by the awardee when support ends. The information is used by the PHS awarding component as a final progress report for each award. Also the information establishes each individual's payback obligation where applicable. This form is also used for trainees supported by Institutional Training Grants and Institutional Career Grants, and is submitted to the PHS by grantee institutions on behalf of those individuals.

PHS 6031 - The Payback Agreement is sent in at the time the individual activates, certifying agreement to fulfill the payback provisions. This form is used in conjunction with the PHS 416-5 Activation Notice.

PHS 6031-1 - The Annual Payback Activities Certification is completed by individuals to show whether payback service has been engaged in and whether such service is acceptable. The information is used by the PHS to administer the legislated payback requirements of the Kirschstein-NRSA program. Without the information it would not be possible to determine acceptable payback service and to credit the account of individual recipients.

This request is for approval of the continued usage of these information collections as described above.

A.3 Use of Information Technology and Burden Reduction

a. Transitioning to the SF424 (R&R) and Electronic Submission through Grants.gov

PHS is an active participant in Federal-wide electronic grant initiatives to improve efficiencies, harmonize data collection among Federal grant making agencies, and provide one simple, unified electronic portal through which applicants may find funding opportunities for, and request Federal support from, 26 different grant-making agencies. One such initiative, Grants.gov, provides a standardized, unified interface for all agencies to announce their grant opportunities, and a single, secure, and reliable source for all grant applicants to find and apply for those opportunities. All these efforts share a goal of unifying and simplifying the grant application process, and ultimately eliminating paper submissions and unnecessary applicant burden. PHS utilizes Grants.gov Find for posting 100% of all funding opportunities. PHS uses Grants.gov Apply for the majority of funding opportunities and has transition plans in place to move the remaining programs into Grants.gov Apply over the next few years.

Another Federal-wide streamlining initiative affecting applications has been the work of the interagency R&R Working Group, which represents 16 Federal agencies supporting research. This group developed the SF424 Research and Related (R&R) data set, a common set of over 250 data elements and uniform reporting requirements arranged in data components to be used by all research

and related grant-making agencies. The SF424 (R&R) is separately approved by OMB under OMB Number 4040-0001, and is therefore not covered by this submission.

The SF424 (R&R) data set includes much of the data needed for PHS programs, however, there remain unique data and information requirements particular to PHS programs. Therefore, NIH has created agency-specific PHS 416 data components and instructions to be used in conjunction with the SF424 (R&R) for electronic submission of individual fellowship applications through Grants.gov. NIH and AHRQ expect to transition individual fellowship applications to electronic submission in calendar year 2009. This clearance package includes the entire set of 416 forms and instructions that are used for paper submission as well as the 416 data elements that will be used in combination with the Federal-wide SF424 (R&R) (Attachment 9) once individual fellowships have transitioned.

Since 2005, NIH and other PHS agencies have made significant strides to transition grant mechanisms to electronic submission through Grants.gov. To date, 80% of grant mechanisms have successfully transitioned. As indicated above, these applications utilize a combined package comprised of the SF424 (R&R) dataset and agency-specific data components.

Applications that have not yet transitioned to electronic submission continue to submit paper applications which are scanned and managed electronically upon receipt at NIH. There is need to maintain essentially dual applications processes until all NIH grant programs transition to electronic submission.

b. eRA Commons

NIH also continues to enhance the electronic Research Administration (eRA) Commons. This electronic infrastructure provides for the secure agency receipt of applications submitted electronically through Grants.gov, and for electronic review of competing applications. The eRA Commons supports electronic administration for grantees and agency staff of the full grants life cycle, from submission to

closeout. It allows grantees to conduct business electronically, and automatically transfers information to the NIH enterprise database, IMPAC II, for processing. It is used by PHS agencies serviced by NIH for the electronic administration of awards.

All relevant business areas--application receipt, referral, review, council, grants management, award processing, program and fiscal administration, reporting and closeout--are accommodated in the eRA Commons. This initiative represents a significant commitment to improve administrative operations through information technologies and reengineering of business processes. eRA includes the functionality for the following grant processes:

1) *Just-In-Time* allows submission of certain data elements in competing applications to be provided electronically later in the review process, and only by those applications likely to be funded. Electronic submission of the Just-In-Time elements eliminates the paper submission and processing of information, and significantly reduces burden on the applicant because the information is *only* requested when the agency expects to fund an application. Just-in-Time includes system-generated e-mails notifying applicants when information should be submitted. These centralized e-mail notifications assure standardization of these requests across all NIH Institutes/Centers.

2) *Progress Report Notification* is 100% electronic. Sponsoring Institutions can electronically access all progress report due dates, and through the eRA Notification system individual fellows receive electronic reminders of due and overdue progress reports. The eRA Commons is also a source of information for grantee institutions on progress report due dates, and provides pre-populated progress report face pages that utilize existing data, also reducing applicant burden. Combined efforts in this area have completely eliminated the hard copy notification process previously in place.

3) *Other electronic notifications* in use for NIH applicants include e-mails at various stages of the application process: application receipt, application assignment, change of assignment, review outcome, and summary statement availability. These e-mail notifications completely eliminate the paper notification processes previously in place.

4) xTrain is a system in the eRA Commons that allows institutions to electronically submit the information required on the PHS 2271 Statement of Appointment (OMB 0925-0001, Exp. 11/2010) and the PHS 416-7 Termination Notice, from trainees on Institutional NRSA's and Individual Fellowships. The xTrain system allows institutional staff to create, route and submit appointment forms and termination notices and to track the status and timing of these actions. Once this information is captured electronically, it reduces the amount of information required of the trainees at the time of termination. Some of the information on the PHS 416-7 Termination Notice is "auto-filled" from the data collected on the electronic PHS 2271 or from the individual fellowship application.

5) *Other eRA Commons functionality* in production includes electronic submission of post-award reporting: Financial Status Reports (SF 269), close-out documents, and no-cost extension notifications. The Internet Assisted Review (IAR) function allows for the peer review process to be conducted in a completely electronic environment.

c. User-friendly Forms

In those instances where paper applications are still in use, NIH and AHRQ use fill-able Microsoft Word forms, increasing efficiency while reducing burden on applicants. Forms are available in fillable Word and PDF formats.

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

Similar information does not exist, and thus there is no other method for collection. Information requested as part of the competing application process relates to new and unique requests for funding to support work not previously proposed. In accordance with policy, submissions of identical applications to one or more components of the PHS are not allowed, and similar grant applications with essentially the same research focus will not be accepted from the same applicant organization. For xTrain, information is captured and stored electronically. This then reduces the amount of information required of the trainees and individual fellows at the time of termination. For non-competing applications (PHS 416-9), a computer-generated face page is available to the applicant in the eRA Commons with items 1 through 6 pre-populated, by data in NIH's eRA system collected when the PHS 416-1 was submitted.

There are a number of ongoing Federal-wide initiatives that will impact forms and datasets. NIH and AHRQ actively participate in these Federal-wide initiatives and therefore are poised to adjust agency-specific forms as applicable.

A.5 Impact on Small Businesses or Other Small Entities

Applicants are individuals applying for Individual Ruth L. Kirschstein National Research Service Awards. Before submitting an application, an applicant must arrange for an appropriate institution to sponsor them and acceptance by a specific sponsor, who will supervise the training and research

experience. The institutional setting may be a private or public institution, including a Federal laboratory or a small business.

A.6 Consequences of Collecting the Information Less Frequently

The basic information in the application (PHS 416-1) is a one time collection; the PHS 416-9 is a progress report that relates to the original application for previously recommended support; payback agreement (PHS 6031), and payback certification (PHS 6031-1) are required by governing law and regulations.

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

The information collection is consistent with the guidelines in 5 CFR 1320.5.

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

An announcement was placed in the Federal Register, March 12, 2008 (Volume 73, Number 49, Page 13242) for public comment on the data collection project, thereby providing the grantee community an active voice in revisions. No comments were received. Comments were also solicited from within NIH and from AHRQ agency staff.

A.9 Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents.

A.10 Assurance of Confidentiality Provided to Respondent

Release of information is fully explained in the application PHS 416-1 and progress report 416-9, and other related grant information collections. The PHS maintains applications and grant records as part of a system of records defined by the Privacy Act: [09-25-0036](#), Extramural Awards and Chartered Advisory Committees (Attachment 11).

A.11 Justification for Sensitive Questions

Data from the Personal Data page (part of the initial application PHS 416-1) is encrypted as well as used only for statistical purposes and is removed from the application upon receipt and assignment. Provision of the data is completely voluntary and does not affect the review, or any right, benefit or privilege of the applicant. The data is not part of the application that is reviewed by the Scientific Review Group or the funding component. All data are confidential and are maintained in a Privacy Act record system ([09-25-0036](#)). All analyses conducted on date of birth, gender, and race/ethnicity report aggregate statistical findings only and do not identify individuals. The aggregate data is used by PHS to monitor the operation of review and award processes to detect and appropriately deal with any instances of real or apparent inequities with respect to diversity of applicants.

The PHS requests the last 4 digits of the Social Security Number for the purpose of accurate identification, referral, and review of applications, and for efficient management of PHS grant programs. No individual will be denied any right, benefit, or privilege provided by law because of refusal to disclose Social Security Number. The full Social Security Number continues to be requested on forms related to the payback obligation. The Social Security Number is particularly important for maintaining effective communication with former fellows who have incurred a payback obligation through their participation in the NRSA Program. Failure to provide it may seriously diminish the PHS's ability to credit the payback account of the proper fellow.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

Burden on applicants and grantees is associated with the forms and all proposed changes in the forms; there is no burden associated with regulatory language.

The estimated average time to complete the PHS 416-1 remains constant at 20 hours. The estimated average time to complete the PHS 416-9 remains at 15 hours. The estimated average time to complete the PHS 416-5 remains at .08 hours. The estimated average time to complete the PHS 416-7 remains at .50 hours. The estimated average time to complete the PHS 6031 remains at .08 hours. The estimated average time to complete the PHS 6031-1 remains at .33 hours. The estimated average time to complete the reference letters remains at .75 hours.

Since each of these forms serves a different purpose, the number of respondents differs depending on the form used. The annual hour burden is estimated at 98,000 for the PHS 416-1; 27,480 for the PHS 416-9; 120 for the PHS 416-5; 404 for the PHS 416-7; 49 for the PHS 6031 and 1,848 for the PHS 6031-1. The annual hour burden for referees completing reference letters is 14,400.

The number of respondents has been adjusted to reflect the current volume of applicants and the reductions of the payback requirements for the NRSAs. The proposed OMB inventory burden for this collection is 142,301 hours.

A.12-1 Estimates of Hour Burden

| Form # | Form Name | Estimated Number of Respondents | Average Number of Hours Per Response | Annual Hour Burden |
|---------------|---|--|---|---------------------------|
| PHS 416-1 | National Research Service Award Individual Fellowship Application | 4,900 | 20 | 98,000 |
| | Reference Letters | 19,200 | .75 | 14,400 |
| PHS 416-9 | Individual Fellowship Progress Report for Continuation Support | 1,832 | 15 | 27,480 |
| PHS 416-5 | Activation Notice | 1,500 | .08 | 120 |

| | | | | |
|---------------|---|---------------|-----|----------------|
| PHS 416-7 | Termination Notice | 809 | .50 | 405 |
| PHS 6031 | Payback Agreement | 613 | .08 | 49 |
| PHS 6031-1 | Annual Payback Activities Certification | 5,600 | .33 | 1,848 |
| TOTALS | | 34,454 | | 142,302 |

Annualized Cost to Respondents

Cost to PHS 416-1 respondents $\$35 \times 98,000 = \$3,430,000$

Cost to referee $\$35 \times 14,400 = \$504,000$

Cost to PHS 416-9 respondents $\$35 \times 27,480 = \$961,800$

Cost to PHS 416-5 respondents $\$35 \times 120 = \$4,200$

Cost to PHS 416-7 respondents $\$35 \times 404 = \$14,140$

Cost to PHS 6031 respondents $\$35 \times 49 = \$1,715$

Cost to PHS 6031-1 respondents $\$35 \times 1,848 = \$64,680$

TOTAL = \$4,980,535

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

Other annual costs to respondents or record keepers are associated with customary and usual business or practices of organizations applying for PHS funding.

A.14 Annualized Cost to the Federal Government

The estimated annual cost to NIH is approximately \$17,920,000 per year. This figure represents the approximate cost for the administration and management of the NIH extramural research program, including application receipt, review, and the administration of awarded applications. The extramural research program is a \$22,400,000,000 enterprise (80% of the NIH budget).

A.15 Explanation for Program Changes or Adjustments

The difference listed in the burden totals represents an increase of 18,267. This is attributable to the significant increase in number of applications received and the number of applications funded, and respondent count adjustments.

[A Summary Table of Significant Changes is Attachment 10.](#)

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

This request is for approval of use of forms related to administration of PHS research programs; there is no tabulation, publication, or project time schedule.

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

The OMB Number and expiration date are displayed on the paper forms. However, forms developed by Grants.gov for electronic submission will only display the OMB Number. Expiration dates will not be displayed to avoid the need for Grants.gov redevelopment when no data elements change on the form in future years.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

This project conforms to all of the 5 CFR 1320.9 requirements; no exceptions are requested.