

Supporting Statement A

PHS Applications and Pre-award Related Reporting
0925-0001

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PHS Applications and Pre-award Related Reporting

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Supporting Statement

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SUPPORTING STATEMENT

Overview

The National Institutes of Health (NIH) and other Public Health Service (PHS) agencies currently use the Research and Research Training Grant Applications and Related Forms (0925-0001) and Ruth L. Kirschstein National Research Service Award (NRSA) Applications and Related Forms (0925-0002). Both 0925-0001 and 0925-0002 will expire on June 30, 2012. In 2009, application and pre-award related forms were simultaneously submitted under both 0925-0001 and 0925-0002. This 0925-0001 submission consolidates application and other related pre-award reporting requirements previously collected under 0925-0001 and 0925-0002. Post-award reporting requirements previously collected under 0925-0001 and 0925-0002, and the New Research Performance Progress Report (RPPR), are similarly consolidated and concurrently submitted under 0925-0002.

This reconfiguration represents a logical consolidation for the following reasons:

- Grouping pre- and post-award reporting requirements is a logical configuration reflecting typical functional division of responsibilities, authorities, and business process in the agencies as well as at grantee institutions. For example, at the agency some pre-award activities are governed by Peer Review regulations and are the responsibility of Scientific Review Officers and peer review committees and councils along with Program Officials and Grants Management Officials; while post-award activities are managed solely by Grants Management Officers and Program Officials. Responsibilities at grantee institutions are correspondingly often divided into pre-and post-award activities.

- Another effect of this reconfiguration is to eliminate the need for a separate OMB approval of forms created for programs established under the Ruth L. Kirschstein National Research Service Award (NRSA) Program. Placing the 416-9 NRSA Individual Fellowship Progress Report for Continuation Support into the same information collection cycle as the RPPR presents an opportunity to discontinue the maintenance of a separate OMB approval for NRSA related forms (previously cleared under 0925-0002). Accordingly, all collections previously cleared under 0925-0002 are now placed under the appropriate pre-award (0925-0001) or post-award (0925-0002) clearance.

Attachment 1 demonstrates the former and revised content of the information collections.

The information collections included in this submission are:

1. PHS 398 [paper] Public Health Service Grant Application Forms and Instructions
2. PHS 398 [electronic] Public Health Service Grant Application component forms and agency specific instructions used in combination with the SF424 (R&R)
3. PHS Fellowship Supplemental Form and agency specific instructions used in combination with the SF424 (R&R) forms/instructions for Fellowships [electronic]
4. PHS 416-1: Ruth L. Kirschstein National Research Service Award Individual Fellowship Application Instructions and Forms used only for a change of sponsoring institution application [paper]
5. PHS Supplemental Grant Application Instructions for use with PHS 398 [paper], PHS 398 [electronic], PHS Fellowship Supplemental Form [electronic], and PHS416-1 [paper] application instructions.
6. Instructions for a Change of Sponsoring Institution for NRSA Fellowships (F30, F31, F32 and F33) and non-NRSA Fellowships
7. PHS 416-5: Ruth L. Kirschstein National Research Service Award Individual Fellowship Activation Notice
8. PHS 6031: Ruth L. Kirschstein National Research Service Award Payback Agreement

Justification

A.1. Circumstances Making the Collection of Information Necessary

PHS 398: The Public Health Service Grant Application (PHS 398) is used by applicants to request federal assistance for research and research-related training. PHS 398 application enables public and private organizations to compete for funds for traditional investigator-initiated research projects appropriated to the various components of the PHS and to request access to databases and other PHS resources. Several PHS agencies make such awards using this application: National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substance and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and the Indian Health Service (IHS). In addition, two offices within the HHS Office of the Secretary (OS), Office of Population Affairs (OPA) and Office of Family Planning (OFP) are serviced by NIH for grant programs and also use this application. In addition, the Biographical Sketch format page is used by the Health Resources and Services Administration (HRSA).

The PHS 398 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 awards are authorized under 42 USC 241; 42 USC 216; 42 USC 285; 42 USC 286; 42 USC 300 and 42 USC 288. This information collection is currently approved under OMB 0925-0001, expiration June 30, 2012. Information collection requirements are specified in regulations governing the PHS research program, including 42 CFR Part 52, 42 CFR 66.204, and 45 CFR 74.

In addition to the Research Project Grant, the PHS uses these applications for programs such as: Institutional Training Grants including Ruth L. Kirschstein National Research Service Awards (NRSA) and other specialized training programs, Research Career Development Awards (CDA), Program Project and Center Grants, Conference Grants, Cancer Center Support Grants, Biotechnology Resources Grants, Academic Career Awards, Academic Research Enhancement Awards, and for access to agency sponsored resources. These awards are established under authorities such as 42 USC 241 and 42 USC 288. Applicable regulations include: 42 CFR 52.4 specifying the content of the grant application, 42 CFR 52a.4 specifying the content of the center grant application, and 42 CFR 66.204 specifying the content of the NRSA application. Awards are identified in the Catalogue of Federal Domestic Assistance (Attachment 2).

SF424 (R&R) and PHS398 Forms: The large majority of award applications to NIH and other PHS agencies are submitted electronically through Grants.gov using the Federal-wide SF424 (R&R) application data set. The SF424 (R&R) is separately approved by OMB under OMB Number 4040-0001. NIH and other PHS agencies also require submission of additional PHS398 forms for collecting agency-specific data not included in the Federal-wide forms as part of the application data set.

NIH and other PHS agencies are continuing to transition to full electronic submission through Grants.gov and use of the Federal-wide SF424 (R&R) application data set. During the transition period there is a need to maintain essentially dual applications processes: complete PHS 398 forms and instructions for programs that have yet to transition to electronic submission and are submitted in hard copy; and PHS 398 component forms for collecting agency-specific data unique to PHS programs that are not part of the Federal-wide SF424 (R&R) data set. The PHS 398 presented in this clearance package includes the 398 forms that are modified since the last OMB approval (Attachment 3), the entire set of PHS 398 instructions

(Attachment 4), and the PHS 398 component forms and agency specific instructions used in combination with the Federal-wide SF424 (R&R) (Attachment 5). Use of the PHS 398 paper application diminishes as programs transition to electronic submission, particularly for complex applications such as Research Program Projects and Centers (see Section 3. Use of Information Technology and Burden Reduction). At this time 95% of programs have transitioned to electronic submission that use the SF424 (R&R) and PHS 398 component forms.

PHS Fellowship Supplemental Form [electronic]: All new and competing individual fellowship applications to NIH and AHRQ are submitted electronically through Grants.gov using the Federal-wide SF424 (R&R) application data set. However, NIH and AHRQ also require submission of additional Fellowship-specific data not included in the Federal-wide forms. The Public Health Service Fellowship Supplemental Form is the form used to collect such agency and fellowship program specific information. It is used by applicants to request federal assistance for research-related training (see Attachment 6 for forms and instructions). This form is used only by 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 awards are established under statutory authorities contained in the PHS Act, as amended (42 USC 288) and are authorized in accordance with 42 USC 288 and 42 CFR 66. Information collection requirements specified in the regulations governing the NRSA program, include 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 June 30, 2012).

Multiple uses of the PHS Fellowship Supplemental Form: 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; Minority Access to Research Career (MARC) Kirschstein-NRSA Faculty Fellowships; MARC Visiting Scientists Fellowships; Postdoctoral Medical Informatics Fellowships and Senior Medical Informatics Fellowships.

PHS 416-1: The Public Health Service Grant Application PHS 416-1, Ruth L. Kirschstein National Research Service Award Individual Fellowship Application [paper] is used **only** for a change of sponsoring institution application (Attachments 7 and 8). NIH is developing an electronic business process for handling change of sponsoring institution applications; thus the use of paper forms will eventually be eliminated.

PHS 416-5: Ruth L. Kirschstein National Research Service Award Individual Fellowship Activation Notice (Attachment 9) 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 6031: Ruth L. Kirschstein National Research Service Award Payback Agreement certifies agreement to fulfill the payback obligation in service or dollars based on the length and amount of support (see Attachment 10 for PHS 6031 instructions and form). The PHS 6031 is used by NIH and AHRQ and HRSA.

A.2. Purpose and Use of the Information Collection

Information collected 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 Agency missions in a highly competitive fiscal environment, and for program management, planning, budgeting, appraisal of progress, and reporting to Congress and the public. Information received from the current collection enables PHS agencies to continue to receive research and training applications from the research community and to fund new and competing awards.

PHS 398 - The PHS 398 comprises the majority of the respondent burden and is used by applicants, staff, and consultants of PHS as follows:

- i. by applicants to compete for funding for research, training, and related activities, and to request access to agency resources;
- ii. by grantees to comply with administrative and policy requirements of terms and conditions of award;
- iii. by the NIH Center for Scientific Review, Division of Receipt and Referral, to evaluate eligibility of the applicant, completeness of the application, and to determine the appropriate assignment to a Scientific Review Group and PHS awarding component;
- iv. by Scientific Review Groups to evaluate the scientific and technical merit of the application in accord with 42 CFR Part 52h;

v. by the PHS to process awards, manage programs, and analyze agency support of mission critical research activities;

vi. by the PHS to determine fiscal benefits and administer awards in compliance with public and program policies and all award terms and conditions.

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PHS 416-1 - The paper 416-1 is used only for post-award change of institution (T-7s) and successor-in-interest actions.

PHS Fellowship Supplemental Form and agency specific instructions used in combination with the SF424 (R&R) forms/instructions for Fellowships [electronic] - The electronic agency-specific component for NRSA and other individual fellowship applications is the PHS Fellowship Supplemental Form. The basic application which comprises the majority of the respondent burden, is used by applicants, staff and consultants of NIH and AHRQ and fulfills the same purpose as the PHS 398 (identified in the previous section under items i. through vi.) except is used for NRSA and other individual fellowships.

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 6031 – The 6031 Payback Agreement certifies an individual’s agreement to fulfill a payback obligation.

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 granting 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. Grants.gov provides a standardized interface for agencies to announce their grant opportunities, and a single, secure, and reliable source for all grant applicants to find and apply for those opportunities. These efforts ultimately eliminate paper submissions and unnecessary applicant burden.

PHS utilizes *Grants.gov Find* for posting 100% of all funding opportunities; *Grants.gov Apply* is used for the majority of program opportunities. To date, 95% of grant programs have successfully transitioned to electronic submission. Complete transition of all programs to *Grants.gov Apply* is dependent upon Grants.gov ability to accommodate complex multi-project programs. Although this requires significant technical development, NIH is working closely with Grants.gov to develop a process for submission of complex multi-project applications using existing SF424 (R&R) forms and the PHS398 forms included in this collection. Pilot implementation of the new system is currently proposed to begin in January 2013 with full implementation anticipated by January 2014. Once the implementation is complete, 100% of NIH grant applications will be submitted electronically through Grants.gov.

As discussed under 1. Circumstances Making the Collection of Information Necessary, unique data and information requirements particular to PHS programs are provided through agency-specific PHS 398 data components and instructions to be used in conjunction with the SF424 (R&R). Programs that have not transitioned to electronic submission continue to utilize paper applications comprised solely of PHS 398

forms, which are scanned and managed electronically upon receipt at NIH. Similarly, the paper 416-1 is used only in a change of institution, whereas, the electronic PHS Fellowship Supplemental Form is used in combination with the SF424 (R&R) forms and instructions for fellowships.

Consolidation of Supplemental Application Instructions

The Public Health Service Supplemental Grant Application Instructions will minimize applicant confusion caused by multiple sets of application instructions with similar or identical information. It consolidates the former Parts II and III of each set of application instructions into one document to be used in conjunction with all sets of instructions (398 paper, 398 electronic, Fellowship, SBIR). See Attachment 11 for the “Supplemental Instructions for Preparing the Protection for Human Subjects Section of the Research Plan” and “Policies, Assurances, Definitions, and Other Information.” The only changes to these instructions are policy updates and editorial clarifications.

Electronic Type 3 Submission

To meet NIH and Federal-wide goals for increasing electronic grants processes, current efforts are underway to develop the electronic Type 3, administrative supplement, submission. This will standardize the application process and reduce burden on grantees; eliminate the use of a paper 398 form for these requests; enable NIH to handle an increasing number of administrative supplement requests; reduce costs by standardizing the processing of administrative supplement requests; and systematize data collected on the diversity and reentry programs.

Two pilots, one through Grants.gov and one through a "streamlined system" in the eRA Commons, began February 2012. Both are expected to standardize the administrative supplement request process and reduce the application burden of grantees. The two pilots are only available for administrative supplement (non-competing Type 3) requests that do not involve a change of scope or specific aims,

and which do not require peer review. All competitive Type 3 requests (also called Competitive Revisions) are handled through separate processes and are not included in these pilots.

Electronic Type 7

NIH's ongoing effort for conversion of electronic operations includes transitioning Change of Institution (Type 7) requests, Successor-in-Interest (Type 6) actions, and transfers of Fellowship (Type 7) applications (currently submitted on 416-1). The paper 416-1 is used only for post-award change of institution (Type 7); NIH anticipates phasing out use of the paper 416-1 as a system for accepting electronic Fellowship applications is implemented in FY2013. The pilot for Type 7 Electronic Submission is expected in 2012.

Electronic Complex Applications

To date, 95% of competing NIH applications are submitted electronically through Grants.gov. The remaining "Complex" applications include multiple independent subprojects with separate budgets, a feature not currently supported by Grants.gov. As a result, these must still be submitted through a paper process. To meet the goal of receiving all competing applications electronically, NIH is partnering with Grants.gov to develop a new system that accommodates multiple subprojects utilizing the SF424 (R&R) and PHS 398 family of forms. The system will be piloted beginning in January 2013 and will be implemented over the course of the year. Once complete, NIH expects significant applicant burden reductions by 1) using electronic systems to eliminate redundant data collections; 2) reducing confusion by using a single form set for all competing applications; and 3) allowing system-to-system users to submit complex applications directly through Grants.gov.

b. eRA Commons

The electronic Research Administration (eRA) Commons is an electronic infrastructure that provides for the secure agency receipt of applications submitted electronically through Grants.gov, and electronic administration by grantees and PHS staff for the complete grant life cycle. It allows grantees to conduct

business with PHS electronically, and automatically transfers information to the NIH enterprise database, IMPAC II, for processing. All relevant business areas--application receipt, referral, review, council, grants management, award processing, program and fiscal administration, reporting, and close-out--are accommodated in the eRA Commons. This initiative represents improved administrative operations through information technologies and reengineered business processes. eRA also includes the functionality for the following pre-award grant processes:

1) *Just-In-Time (JIT)* allows certain data elements required for competing applications to be submitted electronically and later in the review process (after peer review but prior to funding), and only by those applications likely to be funded. In addition to eliminating paper submission and unnecessary agency processing, JIT significantly reduces applicant burden because information is *only* requested, through centralized system-generated e-mail notifications, when potential funding is anticipated. The JIT module's capabilities have recently expanded to allow submission of any text attachment collected in a grant application, allowing potential expansion of JIT and additional burden reductions. Additionally, NIH anticipates mandatory electronic submission of JIT materials in the Summer/Fall of 2012.

2) *Personal Profile* provides principal investigators and reviewers with a secure electronic environment to maintain in the NIH system information concerning degrees, affiliations with institutions, and other professional information, which associates profiles with NIH grant awards. The majority of the data collected is a one-time collection; however institutional affiliations are updated as necessary. This data is used by the agencies to evaluate demographic information, determine eligibility for programs, and for workforce analysis. It is also used to prepopulate required data in post-award business processes. All of the data elements in the Personal Profile are found in application forms used by the agencies which are already approved for collection under OMB Clearances 0925-0001 and 4040-0001. (See Attachment 12 for the data elements of the eRA Commons Personal Profile.)

c. User-friendly Forms

Where paper applications and forms are still in use, NIH uses fillable Word forms, increasing efficiency while reducing burden on applicants; forms are also available in PDF format.

d. Use of OER Websites

The NIH Office of Extramural Research (OER) public website is used to provide access to all forms, instructions and business processes in an electronic, accessible environment.

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 are not accepted from the same applicant organization.

PHS 398:

NIH actively participates in a number of ongoing Federal-wide initiatives that impact forms and datasets. The Federal-wide SF424 (R&R) is intended to coordinate application data requirements across Federal agencies. When the transition to electronic submission is complete, the PHS 398 will comprise of only those data elements that are unique to PHS programs (now the 398 component forms). All agency-specific data requirements are shared within the Federal-wide R&R Working Group of 16 research agencies to determine if other agencies have similar data needs. When common needs exist, the data is added to the SF424 (R&R) forms and then also removed from the agency-specific forms. Some of the changes noted in

A.15 below are a result of this collaborative process. At this time, other (non-PHS) agencies do not have a need for the 398 specific data components.

A.5. Impact on Small Business or other Small Entities

The procedures for small businesses and other small entities are the same as for other applicants and grantees. The Small Business Innovative Research and Small Business Technology Transfer (SBIR/STTR) grants were the first NIH programs to transition to electronic submission. The impact on small business or other small entities is anticipated to be negligible.

A.6. Consequences of Collecting Information Less Frequently

The basic information in the PHS 416-1 is a onetime collection. PHS 6031, the payback agreement, is required by governing law and regulations. All other forms in this package represent one time information collections. It is not possible to collect the information less frequently.

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

Approval is requested to continue to receive an original and 5 copies of PHS 398 applications submitted on paper (approximately 10% of applications), a deviation from 5 CFR 1320.5 (c). The additional 3 copies are required in order for the Center for Scientific Review to handle an annual workload of approximately 85,000 competing applications (paper and electronic) in a dependable manner and within a rigorous time schedule. Successful applicants can expect to initiate research approximately 10 months from the NIH receipt date. This is critically important to the dynamic nature of research, to the research community, and to funding agencies. NIH is committed to completing the processing, review and funding of applications

within this timeframe. Applicant submission of an additional 3 copies is critical to meeting this goal and an accelerated processing timetable for the expedited review of AIDS research applications.

Additionally, limited approval is requested to receive a CD copy of certain attachments to PHS 398 applications submitted on paper. Historically, NIH has scanned the paper copies to be used by reviewers to be used in electronic systems. However, certain high-resolution scientific images cannot be properly reproduced through scanning and require NIH to receive an original electronic copy of the attachment. Under current plans, NIH will transition to electronic receipt of complex applications and does not anticipate needing to utilize this authority once that transition is complete. However, unforeseen obstacles may possibly delay the system's implementation and force NIH to require an additional CD copy of attachments containing high-resolution images.

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

An announcement was placed in the Federal Register, Vol.77, No.43, March 5, 2012 for public comment on the data collection project, thereby providing the grantee community an active voice in the revision process. One public comment was received which asked for clarification about new reporting burdens. It was noted in follow-up that NIH has seen a 21% increase in competing applications since the last clearance which has resulted in an increase in the burden hours. We are also transitioning to the Research Performance Progress Report (RPPR) as mandated by OMB. Comments were also solicited from staff within NIH and the PHS agencies IT services.

Other consultations occur regularly at NIH Regional Seminars on Program Funding and Grants Administration held twice each year. Participation in the Federal Demonstration Partnership (FDP) (<http://thefdp.org>), and meetings of professional organizations such as the National Council of University

Research Administrators (NCURA), Society for Research Administrators (SRA), and the Council on Government Relations also provides an avenue of productive communication with the grantee research community. Such meetings provide for exchange of information on the peer review system, preparation of applications, and other administrative aspects of the PHS programs. All questions, comments and discussions from these meetings and throughout the year are duly noted and considered when modifying grant related information collections.

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 Respondents

The Privacy Act applies to this collection. The NIH maintains application and grant records as part of a system of records as defined by the Privacy Act: NIH 09-25-0036, *Extramural Awards and Chartered Advisory Committees (IMPAC 2)*, *Contract Information (DCIS)*, and *Cooperative Agreement Information*, HHS/NIH: <http://oma.od.nih.gov/ms/privacy/pa-files/0036.htm>. The SORN was published in the Federal Register on September 26, 2002 (Vol. 67, No. 187). Release of information is fully explained in all grant related information collections.

A.11. Justification for Sensitive Questions

The eRA Commons Personal Profile requests the last four digits of the Social Security number for purposes of accurate identification, referral, and efficient management of PHS grant programs. Provision of the partial Social Security number is voluntary and no individual will be denied any right, benefit, or privilege provided by law because of refusal to disclose the partial Social Security number. This data is

not part of the application reviewed by Advisory Committees or the funding component. All analyses utilizing other voluntarily provided data such as month/year of birth, gender, race and ethnicity report aggregate statistical findings only and do not identify individuals. All sensitive data are maintained in a Privacy Act record system (09-25-0036).

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

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 398 [paper] remains at 35 hours. For those activity codes that have transitioned to electronic submission (95% now, 83% previously), NIH continues to estimate that approximately 90% of the burden has shifted to the SF424 (R&R). The remaining estimated average burden for the electronic PHS 398 component forms remains at 22 hours, however, the total number of applications increased from the previous year. The average number of respondents per year is estimated at 84,701 for the PHS 398 (8,389 paper and 76,312 electronic); 4,915 for the PHS Fellowship Supplemental Form; 3,121 for the 416-7; and 1,559 for the PHS 6031. In addition, certain applications require letters, e.g., policy requires applicants requesting \$500,000 or more in direct costs in any one budget year to include a cover letter with the application, and CDA candidates are required to include three separate letters of reference and a letter of support from the candidate's Department head. Reference letters are now submitted electronically through eRA Commons, therefore, reducing burden and increasing efficiency. (Calculation of burden hours for reference letters are incorporated into the PHS Fellowship Supplemental Form.)

Estimates of Hour Burden				
Information Collection Number or Form	Number of Respondents	Frequency of Response	Average Time (hrs) Per Response	Annual Burden Hours
PHS 398 [paper]	8,389	1	35	293,615
PHS 398 [electronic]	76,312	1	22	1,678,864
PHS Fellowship Supplemental Form [electronic]	4,915	1	16	78,640
PHS 416-1	30	1	10	300
PHS 416-5	3,121	1	0.08	250
PHS 6031	1,559	1	0.08	125
TOTALS	94,326	1	21.75	2,051,794

The average hourly rate used for all burden hours (\$35) represents an average of combined clerical (\$15), administrative (\$25), and professional staff (\$45) hourly rates.

Annualized Cost to Respondents					
Information Collection Number or Form	Number of Respondents	Frequency of Response	Average Time (hrs) Per Response	Hourly Wage Rate	Respondent Cost
PHS 398 [paper]	8,389	1	35	\$35.00	\$10,276,525
PHS 398 [electronic]	76,312	1	22	\$35.00	\$58,760,240
PHS Fellowship Supplemental Form	4,915	1	16	\$35.00	\$2,752,400
PHS 416-1	30	1	10	\$35.00	\$10,500
PHS 416-5	3,121	1	0.08 hrs	\$35.00	\$8,739
PHS 6031	1,559	1	0.08 hrs	\$35.00	\$4,365
TOTALS	94,326	1	21.75	\$35.00	\$71,812,769

A.13. Estimates of Other Total Annual Cost 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. There are no additional costs to the respondents.

A.14. Annualized Cost to the Federal Government

The annualized cost to the federal government to administer and manage the entire NIH budget, including intramural programs, is approximately \$1.5 billion. It is not possible to parse the cost of pre award administration with any degree of accuracy. The NIH extramural research program is a \$24.5 billion enterprise (80% of the NIH budget).

A.15. Explanation for Program Changes or Adjustments

This submission represents program changes; previous estimated total burden hours for 0925-0001 was 2,251,500, current estimated total burden hours for 0925-0001 is 2,051,794. This represents a decrease of 199,706 hours since the last approval. This is attributed to the reconfiguration of 0925-0001 and 0925-0002 into pre- and post-award forms as detailed in Attachment 1. Specific program changes for items now under 0925-0001 are described below:

A Summary Table of Noteworthy Changes or Adjustments

Form	Adjustments
PHS 398 Career Development Award Supplemental Form (electronic)	Remove Section 1 “Application Type.” Remove Header for “Section 2. Career Development Activities.” Add new Item 8: “Letters of Support from Collaborators, Contributors, and Consultants.”
PHS 398 Cover Page Supplement (electronic)	Removed data fields no longer needed due to upcoming changes in the SF424 (R&R) Cover Component: Remove the “Clinical Trial?” checkbox field in Item #2. Delete all of Item #3: “Applicant Organization Contact.” Relocated data fields formerly contained on the PHS398 Checklist form for electronic submission.
PHS 398 Checklist	For electronic SF424 (R&R) submissions, data moved to the PHS 398 Cover Page supplement, thus eliminated as a separate form component. Still retained for paper based.
PHS 398 Form Page 2 (paper)	Revised instructions for Human Embryonic Stem Cells requiring applicants not able to reference a specific line to provide a strong justification why one cannot be referenced at this time.
PHS 398 Research Plan (electronic)	Remove Section 1 “Application Type.” Remove Header for “Section 2. Research Plan Attachments.” Include potential field for “Other Appendix Files.”

	Under the “Targeted/Planned Enrollment Table format page” added the category “More Than One Race” to be consistent with the Inclusion Enrollment Report and OMB Standards for Data on Race and Ethnicity.
PHS 398 Research Training Program Plan Form (electronic)	Remove Section 1 “Application Type.” Remove Header for “Section 2. Research Training Program Plan Attachments.”
PHS Fellowship Reference Form	Eliminate Fellowship Reference Form and replace with general format and requirements for reference letters. Align some Fellowship reference letter evaluation criteria with those used for career development award reference letters.
PHS Fellowship Supplemental Form	Remove data field no longer needed due to upcoming changes in the SF424 (R&R) Cover Component: Remove Section 7 “Clinical Trial?”
PHS 6031 Payback Agreement	Add on page 1, “This agreement is a required condition of award.” Under section VI, add “The completed form should be mailed to the awarding Federal Agency Grants Management Office named in the Notice of Award.” For clarity, revise to: “Nine Digit Social Security No. (Required).”

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

There is no tabulation, publication, or project time schedule associated with use of forms.

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

The OMB number will be displayed in all electronic modules and on paper forms. The OMB expiration date is not displayed in electronic modules in order to obviate the need to revise or modify electronic systems solely for date changes. However, the expiration date is noted in all instructions.

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.
