Supporting Statement A for

PHS Applications and Pre-award Related Reporting
[OD/OPERA]
OMB# 0925-0001
Exp., date 10/31/2018

Date: January 23, 2017

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Check off which applies:

- ✓ Revision

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A. Justification

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 and Ruth L. Kirschstein National Research Service Award (NRSA) Applications and Related Forms (0925-0001). 0925-0001 will expire on October 31, 2018. This 0925-0001 revision submission consolidates application and other related pre-award reporting requirements previously collected under 0925-0001. Oversight systems and tools are critical for the NIH to ensure participant safety, data integrity, and accountability of the use of public funds. The NIH has been engaged in a multi-year effort to examine how clinical trials are supported and the level of oversight needed. The collection of more structured information about proposed clinical trials in the PHS applications and pre-award reporting requirements will facilitate the NIH's oversight of clinical trials as well as assist in understanding where needs in the NIH research portfolio may exist. In addition, some of the data collected here will ultimately be accessible to investigators to pre-populate certain sections of forms when registering their trials with ClinicalTrials.gov.
Post-award reporting requirements, including the Research Performance Progress Report (RPPR), are similarly consolidated and concurrently submitted under 0925-0002 (expiration October 31, 2018).

A.1. Circumstances Making the Collection of Information Necessary

PHS 398: The Public Health Service (PHS) Grant Application (PHS 398) is used by applicants to request federal assistance for research and research-related training. The 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, including the 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, which is a part of the application, is also used by the Health Resources and Services Administration (HRSA). Participating agencies in the Small Business Innovation Research and Small Business Technology Transfer (SBIR/STTR) grant programs include the Administration for Children and Families (ACF), CDC, and FDA. The Administration for Community Living (ACL) may participate in the near future as well.

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, with an expiration on October 31, 2018. Information collection requirements are specified in regulations governing the PHS research program, including 42 CFR Part 52, 42 CFR 66.204, and 45 CFR 75.

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 issued under various NIH programs, which are identified in the Catalogue of Federal Domestic Assistance (Attachment 2).

SF424 (R&R) and PHS 398 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 PHS 398 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 PHS 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). A new component form entitled "PHS Human Subjects and Clinical Trials Information" has been added. 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 PHS 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 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 October 31, 2018).

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 for all grant mechanisms; thus the use of paper forms will eventually be eliminated.

Biographical Sketch: Grant and cooperative applications require a biographical sketch be completed and uploaded for all senior/key personnel and other significant contributers. There is a General Biographical Sketch Format Page that is available for research grant applications, career development, training grant, and all other non-fellowship application types (see Attachment 9 for format page, instructions, and sample). A Fellowship Sponor/Co-Sponsor can also use this format page. Individual fellowships, R36 dissertation grants, and diversity supplement applicants

should use the Fellowship Application Biographical Sketch Format Page (see Attachment 10 for format page, instructions, and samples).

Data Tables: Institutional Research Training grant applications using the SF424 (R&R) must complete applicable data tables (see Attachment 11 for instructions and samples). The Introduction to the Data Tables provides instructions applicable to all tables, specific instructions for each table, and Sample Data Tables. The Sample Data Tables illustrate the kind of data to include in each table for Kirschstein-NRSA training grant applications. These tables include undergraduate training, predoctoral training, postdoctoral training, short-term training, or a mix of these types. Also included is a set of training tables for international programs.

PHS 416-5: Ruth L. Kirschstein National Research Service Award Individual Fellowship Activation Notice (Attachment 12) 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 13 instructions and form). The PHS 6031 is used by NIH, AHRQ and HRSA.

SBIR/STTR Funding Agreement Certifications: For SBIR and STTR new and competing renewal applications, a funding agreement certification is required to be submitted as part of the NIH Just-In-Time pre-award procedure (see Attachment 16 for instructions and forms). These certifications are necessary to ensure that the applicant meets the Small Business Administration (SBA) size criteria, and that the organization will comply with other program-specific

requirements such as all work must be conducted in the United States and that a minimum amount of work be performed by its own employees within its own facilities, before NIH to can issue an award. Applicant small business concerns that are majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms (e.g. majority VCOC-owned) are required to submit a Certification at time of their application submission (see Attachment 17 for instructions and form). This applies to NIH and CDC small business applicants.

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.

Since the last OMB approval, NIH has worked on enhancing several key policies, which are necessary to continue enhancing the quality of basic and preclinical research, as well as NIH-funded clinical trials. Some policy updates that are included in the 0925-0001 revision request include the following:

i. Biosketch instructions have been rewritten for clarity – using shorter sentences, bullet points, and shorter paragraphs. Clarification on which sections apply for which mechanisms have been updated (i.e., fellowship, career, etc.). No policy changes have been made regarding biosketch instructions.

ii. NIH has redefined the policy for allowable appendix materials, effective for application due dates on or after January 25, 2017.

iii. Development of an optional electronic system submission process to request prior approval from the NIH.

iv. Addition of training tables for international programs.

v. The NIH has been engaged in a multi-year effort to examine how clinical trials are supported and the level of oversight needed. The collection of more structured information about proposed clinical trials in the PHS applications and pre-award reporting requirements will facilitate the NIH's oversight of clinical trials as well as assist in understanding where needs in the NIH research portfolio may exist. In addition, some of the data collected here will ultimately be accessible to investigators to pre-populate certain sections of forms when registering their trials with ClinicalTrials.gov.

This clearance package includes the specific PHS companion forms and application instructions that implement these policy changes.

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.

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 it is used for NRSA and other individual fellowships.

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

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. NIH worked closely with Grants.gov to develop a process for the submission of complex, multi-project applications using existing SF424 (R&R) forms and the PHS 398 forms included in this collection. The new process implemented by Grants.gov, in combination with the Application Submission System & Interface for Submission Tracking (ASSIST) on-line front-end implemented by NIH to support single- and multi-project programs, enabled NIH to accept all competing grant applications electronically through *Grants.gov Apply*. Use of ASSIST as a submission option to Grants.gov is being expanded to other Public Health Service agencies and programs.

As discussed under A.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 - PHS Supplemental Grant Application Instructions will continue to 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 14 for the "Supplemental Instructions for Preparing the Protection for Human Subjects Section of the Research Plan" and "Policies, Assurances, Definitions, and Other Information." Changes to these instructions include policy updates related to inclusion, definitions added for key biological and/or chemical resources and scientific rigor, and editorial clarifications.

Electronic Type 3 Submission - to meet NIH and Federal-wide goals for increasing electronic grants processes, the electronic Type 3, administrative supplement, submission has been developed through Grants.gov and the eRA Commons. This has standardized the application process and reduced burden on grantees, who now have the option of submitting in either system; reduced costs by standardizing the processing of administrative supplement requests; and systematized data collected on the diversity and reentry programs. NIH is working closely with Grants.gov to develop a process for submission of an electronic Type 3 multi-project application.

Electronic Type 7 Submission - 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 changes of institution (Type 7). NIH is working closely with Grants.gov to develop a process for submission of an electronic Type 6 and 7 multi-project application.

Electronic Complex Application Submission - to date, 95% of competing NIH applications are submitted electronically, and the majority are submitted through Grants.gov. “Complex” applications include multiple independent subprojects with separate budgets, a feature not currently supported by Grants.gov. To meet the goal of receiving all competing applications electronically, NIH has partnered with Grants.gov to develop ASSIST, which accommodates multiple subprojects utilizing the SF424 (R&R) and PHS 398 family of forms. ASSIST is also an option for all single project applications.

There has been 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. Electronic submission of JIT materials is mandatory in the eRA Commons.

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 15 for the data elements of the eRA Commons Personal Profile).

c. Electronic submission of data tables via xTRACT - xTRACT supports the optional electronic submission of the new data tables to be used for training grants, institutional career development awards, and research education awards. This module efficiently reduces time spent by applicants preparing and submitting these tables. Use of xTRACT will become mandatory for most NIH institutional training awards, and its use will continue expanding to other NIH research education and institutional career development awards.

d. 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.

e. 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.

f. Prior Approval Requests - the current submission process for prior approval requests is through email or paper submission. NIH has developed an electronic submission option through the eRA Commons for applicants and grantees to submit these requests directly to the appropriate official. Review and approval will happen within this system, which is currently optional for applicants and grantees. Examples of prior approval requests include, but are not limited to: withdraw an application after it has been submitted; and request direct costs of $500,000 or more in any one year. See Attachment 18 for screen shots of this new system.

d. Privacy Impact Assesment (PIA) - NIH grant systems, such as eRA and IMPAC II) are covered by a PIA. See Attachment 19 for the latest copy of NIH's PIA.

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.

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 consist 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

Per Section 200.335 in OMB's Uniform Guidance: If paper copies are submitted, the Federal awarding agency or pass-through entity must not require more than an original and two copies. PHS 398 and 416-1 applications will comply with this requirement.

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 multi-project 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.8.1 Comments in Response to the Federal Register Notice

An announcement was placed in the Federal Register, Vol.81 No.212, pages 76368-76370, on November 2, 2016 for public comment on the data collection project, thereby providing the grantee community an active voice in the revision process. No public comments were received.

A.8.2 Efforts to Consult Outside Agency

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 Privacy Impact Assessment was completed for the databases used in this submission.

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.12.1 Estimated Annualized Burden Hours

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%), NIH continues to estimate that approximately 90% of the burden has shifted to the SF424 (R&R).

The estimated average burden for the electronic PHS 398 component forms has increased to 56 hours due to the development of a new PHS Human Subjects and Clinical Trial Information form. A full burden hour breakdown is provided that totals up to this 56 hour estimate, e.g., each component form has its own burden estimate provided in the chart below. While the total estimate totals to 56 hours, it's important to note that not every form is used in an application. The type of application and budget will drive the forms that are used (e.g., a PHS 398 Modular Budget vs. PHS 398 Training Budget form). For the new PHS Human Subjects and Clinical Trial Information form, the individual burden hour estimate (14 hours) is comprised of human subjects research and clinical trials data collection. Not every application that involves human subjects will include clinical trial information; the type of application will drive the parts of this form that are used (e.g., clinical trial(s) or non-clinical trial human subjects research). The NIH's goal is to create an opportunity for investigators to upload their clinical trial information from the form to facilitate registration in ClinicalTrials.gov, thus reducing user burden.

Similarily, the PHS Fellowship electronic application is made up primarily of the PHS Fellowship Supplemental form. The full burden calculation for a fellowship application has increased to 29 hours,

which is comprised of the PHS Fellowship Supplemental form, and several companion forms that are also included in the PHS (including the new PHS Human Subjects and Clinical Trial Information form).

The average number of respondents per year is estimated at 86,678 for the PHS 398 (4,247 paper and 82,431 electronic); 6,707 for the PHS Fellowship Supplemental Form and 416-5; and 6,217 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). The average number of respondents per year is estimated at 1,500 for the SBIR/STTR funding agreement certifications, and only 6 for the VCOC certification.

A.12-1 Estimated Annualized Burden Hours

Information Collection Forms	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
PHS 398 - Paper	4,247	1	35	148,645
PHS 398/424 - Electronic				
PHS Assignment Request Form	37,120	1	30/60	18,560
PHS 398 Cover Page Supplement	74,239	1	1	74,239
PHS 398 Modular Budget	56,693	1	1	56,693
PHS 398 Training Budget	1,122	1	2	2,244
PHS 398 Training Subaward Budget	561	1	90/60	842

Attachment(s) Form				
PHS 398 Research Plan	70,866	1	10	708,660
PHS 398 Research Training Program Plan	1,122	1	10	11,220
Data Tables	1,515	1	4	6,060
PHS 398 Career Development Award Supplemental Form	2,251	1	10	22,510
PHS Human Subjects and Clinical Trial Information (includes inclusion enrollment report)	54,838	1	14	767,732
Biosketch (424 Electronic)	80,946	1	2	161,892
PHS Fellowship - Electronic				
PHS Fellowship Supplemental Form (includes F reference letters)	6,707	1	12.5	83,838
PHS Assignment Request Form	3,354	1	30/60	1,677
PHS Human Subjects and Clinical Trial Information (includes inclusion enrollment report)	5,030	1	14	70,420
Biosketch (Fellowship)	6,707	1	2	13,414
416-1	29	1	10	290
PHS 416-5	6,707	1	5/60	559
PHS 6031	6,217	1	5/60	518
VCOC Certification	6	1	5/60	1
SBIR/STTR Funding Agreement Certification	1,500	1	15/60	375

Total Annual Burden Hours	----------	**421,777**	----------	**2,150,389**

A.12-2 Annualized Costs to Respondents

Data is from the Bureau of Labor Statistics (http://www.bls.gov/cps/cpsaat39.htm). 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. This request covers many types of research institutions in both the private and public sectors, teaching and non-teaching setting etc. Since the respondent base is so wide, it is difficult to determine an accurate average hourly rates. Therefore the hourly rate used in this table is based on historical NIH figures captured over decades of administering this data collection.

A.12-2 Annualized Cost to the Respondents

Information Collection Forms	Total Annual Burden Hours	Hourly Wage Rate	Total Respondent Cost
PHS 398 - Paper	148,645	$35.00	$5,202,575
PHS 398/424 - Electronic			
PHS Assignment Request Form	18,560	$35.00	$649,600
PHS 398 Cover Page Supplement	74,239	$35.00	$2,598,365
PHS Inclusion Enrollment Report	54,838	$35.00	$1,919,330
PHS 398 Modular Budget	56,693	$35.00	$1,984,255
PHS 398 Training Budget	2,244	$35.00	$78,540
PHS 398 Training Subaward Budget Attachment(s) Form	842	$35.00	$29,470
PHS 398 Research Plan	212,598	$35.00	$7,440,930
PHS 398 Research Training Program Plan (includes data tables)	3,366	$35.00	$117,810
Data Tables	6,060	$35.00	$212,100
PHS 398 Career Development Award Supplemental Form	6,753	$35.00	$236,355
PHS Human Subjects and Clinical Trial Information (includes inclusion enrollment	767,732	$35.00	26,870,620

report)			
Biosketch	161,892	$35.00	$5,666,220
PHS Fellowship - Electronic			
PHS Fellowship Supplemental Form (includes F reference letters)	83,838	$35.00	$2,934,330
PHS Assignment Request Form	1,677	$35.00	$58,695
PHS Human Subjects and Clinical Trial Information (includes inclusion enrollment report)	70,420	$35.00	2,464,700
Biosketch	13,414	$35.00	$469,490
416-1	290	$35.00	$10,150
PHS 416-5	559	$35.00	$19,565
PHS 6031	518	$35.00	$18,130
VCOC Certification	1	$35.00	$35
SBIR/STTR Funding Agreement Certification	375	$35.00	$13,125
Total	**421,777**		**$75,263,633**

A.13. Estimate 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 estimated annual cost to the NIH is approximately $222,054. This information is calculated based on the NIH Policy Analyst and Health Scientist Administrator's salary and percentage of effort devoted to preparing this submission, as well as contractor costs associated with compiling all revisions. These expenses would not have been incurred without this collection of information.

Annualized Cost to the Federal Government

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Government
Federal Oversight					
NIH Grants Policy	14/4	119,776	50%		59,888

Analyst					
NIH Health Scientist Administrator	15/4	140,892	50%		70,446
Contractor Cost					
2 field contractor staff (Ripple Effects Communications, Inc.)		$91,720	50%		91,720
Travel					
Other Cost					
Total					222,054

A.15. Explanation for Program Changes or Adjustments

This submission represents program changes; previous estimated total burden hours for 0925-0001 were 850,756; current estimated total burden hours for 0925-0001 is 2,150,389. This represents an increase of 1,299,632 hours since the last approval. This increase is largely due to the addition of a new PHS Human Subjects and Clinical Trial Information form, as well as a recalculation of burden hour estimates on the following forms: PHS 398 Research Plan, PHS 398 Research Training Program Plan, and PHS 398 Career Development Award Supplemental Form. These estimates are now a more accurate reflection of the data collection requested from applicants.

A Summary Table of Noteworthy Changes or Adjustments:

Form	**Adjustments**
Attachment 3 - PHS 398 [paper]: Public Health Service Grant Application Forms	Implemented a new format and structure for application instructions. The purpose was to enhance clarity of existing instructions. Biosketch instructions have been rewritten for clarity – using shorter sentences, bullet points, and shorter paragraphs. Clarification on which sections apply for which mechanisms have been updated (i.e., fellowship, career, etc.). No policy changes have been made regarding biosketch instructions.

	Instructions have changed so that program income and stem cell information are no longer collected at the Overall Component in multi-project applications. NIH has redefined the policy for allowable appendix materials, effective for application due dates on or after January 25, 2017.
Attachment 4: PHS 398 [paper]: Public Health Service Grant Application Instructions	Added updated language and instructions to the following sections: resubmission applications; biosketch instructions; vertebrate animals; human subjects. Added new PHS Human Subjects and Clinical Trial Information form instructions. Added new appendix policy language.
Attachment 5: PHS 398 [electronic]: Public Health Service Grant Application component forms and agency specific instructions used in combination with the SF424 (R&R)	General updates to SF424 companion forms include reordering current items, moving human subject fields to new PHS Human Subjects and Clinical Trial Information. All instructions are being updated to reflect the changes/updates to the forms below.
Attachment 5B-C: PHS Assignment Request Form	Streamlined instructions
Attachment 5D-E: PHS 398 Cover Page Supplement	Deleted section 1. Human Subjects Renumbered other sections accordingly.
Attachment 5F-G: PHS Human Subjects and Clinical Trial Information	Replaces the PHS Inclusion Enrollment Report; this is now part of the new PHS Human Subjects and Clinical Trial Information form. This new form will be required for applicants proposing human subjects research; will be dynamic and applicants will only be required to answer certain fields if they have clinical trials.
Attachment 5H-I: PHS 398 Modular Budget	Streamlined instructions.
Attachment 5J-K: PHS 398 Training Budget	Streamlined instructions.
Attachment 5L-M: PHS 398 Training Subaward Budget Attachment(s) Form	Streamlined instructions.

Attachment 5N-O: PHS 398 Research Plan	Deleted attachments 5-8 (these are now included in new PHS Human Subjects and Clinical Trial Information form. Renumbered other sections accordingly.
Attachment 5P-Q: PHS 398 Career Development Award Supplemental Form	Deleted attachments 12-15 (these are now included in new PHS Human Subjects and Clinical Trial Information form. Renumbered other sections accordingly.
Attachment 5R-S: PHS 398 Research Training Program Plan	Deleted attachments 10-11 (these are now included in new PHS Human Subjects and Clinical Trial Information form. Renumbered other sections accordingly.
Attachment 6A-B: PHS Fellowship Supplemental Form and agency specific instructions used in combination with the SF424 (R&R) forms/instructions for Fellowships [electronic]	Deleted attachments 12-19 (these are now included in new PHS Human Subjects and Clinical Trial Information form. Renumbered other sections accordingly.
Attachment 8: Instructions for a Change of Sponsoring Institution for NRSA Fellowships (F30, F31, F32 and F33) and non-NRSA Fellowships	Streamlined instructions.
Attachment 9A-C: General Biographical Sketch Format Page, Instructions (use also for Fellowship Sponsor/Co-Sponsors), and Samples	Streamlined instructions Separated Instructions and Format Page into two documents Updated samples
Attachment 10A-C: Fellowship Applicant Biographical Sketch Format Page (use only for individual predoctoral and postdoctoral fellowships, dissertation research grants [R36], and Research Supplements to Promote Diversity in Health-Related Research [Admin Supplement]) and Samples	Streamlined instructions Separated Instructions and Format Page into two documents Updated samples

Attachment 11A-D: Attachment Data tables for use with Institutional Research Training grant applications using the SF424 (R&R)	Updated instructions. Data tables for international programs added.
Attachment 11A-D: Attachment Data tables for use with Institutional Research Training grant applications using the SF424 (R&R)	Updated instructions. Data tables for international programs added.
Attachment 12 - PHS 416-5: Ruth L. Kirschstein National Research Service Award Individual Fellowship Activation Notice	Removed Sponsor signature line.
Attachment 14 - PHS Supplemental Grant Application Instructions for use with PHS 398 [paper], PHS 398 [electronic], PHS Fellowship Supplemental Form [electronic], PHS416-1 [paper], and PHS 2012-02 (SBIR)	Removed instructions for completing human subjects attachments (these are now included in new PHS Human Subjects and Clinical Trial Information form. Streamlined language throughout.
Attachment 18: Prior Approval Screen Shots	Optional electronic submission for existing pre-award prior approval requests.

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 and expiration date will be displayed in all electronic modules and on paper forms.

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.