SUPPORTING STATEMENT

OMB No. 0925-0001/exp. 09/30/07

Research and Research Training Grant Applications and Related Forms

The Public Health Service Grant Application (PHS 398) is used by applicants to request federal assistance for research and research-related training. The application enables public and private organizations to compete for funds appropriated to the various components of the Public Health Service (PHS) and request access to agency sponsored resources. Several Public Health Service Agencies make such awards: National Institutes of Health, Agency for Healthcare Research and Quality, Agency for Toxic Substance and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, and the Indian Health Service. 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, authorized in accordance with 42 CFR Part 52 and 42 CFR 66.204, is currently approved under OMB 0925-0001, expiration 09/2007. Also included under 0925-0001 are:

- PHS 2590: Non-Competing Grant Progress Report used in determining continuation of support during the period of award.
- PHS 2271: Statement of Appointment used to document institutional awardee appointment of individuals under Institutional Training Grants including Ruth L. Kirschstein National Research Service Awards and other specialized research training programs.

- PHS 3734: Official Statement Relinquishing Interest used when an institution relinquishes its rights to a PHS grant.
- HHS 568: Final Invention Statement used in the close-out of an award.
- Interagency Edison Reporting System: Internet-based system developed to meet statutory requirements for reporting of inventions and patents that result from Federal funding agreements (35 USC 202 and 37 CFR 401.8).
- Supplemental Instructions for specialized NIH programs, including Center Grant Programs, authorized under 42 USC 216, 42 USC 285, and 42 USC 300.
- Information collection requirements specified in regulations governing the PHS research program, including 42 CFR Part 52 and 42 CFR 66.204.

Justification

1. Circumstances Making the Collection of Information Necessary

The Application for Public Health Service Grant (PHS 398) is necessary to enable public and private organizations to request funds or access to other benefits from the various PHS Agencies (National Institutes of Health, Agency for Healthcare Research and Quality, Agency for Toxic Substance and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, and the Indian Health Service). The application is required at various times and circumstances in the course of activities proposed to be carried out under the range of the authorized PHS programs. The application is most frequently used to request financial support through the assistance mechanism for traditional investigator-initiated

research projects. However some specialized programs now also use the application to request other benefits from the PHS such as access to databases and other PHS resources.

NIH and other PHS Agencies utilizing the PHS 398 are in the process of transitioning to the Federal-wide application data set, SF424 (R&R), which is submitted electronically. Details of this transition are provided in section *3.*

Use of Information Technology and Burden Reduction.

During this transition period, which is expected to last several more years, there is need to maintain essentially dual applications processes: complete PHS 398 forms and instructions to continued to be used for mechanisms that have yet to transition to electronic submission; 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. Therefore, the PHS 398 presented in this clearance package includes the entire set of data elements and instructions organized as the PHS 398 forms and instructions (Attachments 1 and 5), and the 398 component forms used in combination with the Federal-wide SF424 (R&R) (Attachment 2). As programs continue to transition to electronic submission, the use of the full PHS 398 paper application will diminish. At this time, approximately 80% of funding mechanisms have transitioned to electronic submission and use the SF424 (R&R) and PHS 398 component forms.

The Non-Competing Grant Progress Report (PHS 2590) is used by various PHS agencies of for noncompeting continuation support. Grant funds for subsequent budget periods within an

approved project period are required to be requested annually through the PHS 2590 before the beginning date of the next budget period. The level of funding for the ensuing budget period is determined after review of the progress report by agency program officials, within the framework of the previously approved research project, and the recommended level of support, progress reported, and the availability of funds. (See Attachment 3 for 2590 forms and Attachment 6 for 2590 instructions.)

There are multiple uses of the PHS 398 and PHS 2590. In addition to the Research Project Grant, the PHS uses these applications for programs such as: Institutional Training Grants including Ruth Kirschstein National Research Service Awards (NRSA) and other specialized training programs; Research Development Career Awards; Program Project and Center Grants; Conference Grants; Cancer Center Support Grants; Biotechnology Resources Grants; Academic Career Awards; Academic Research Enhancement Awards, and the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Grant Programs; and access to agency sponsored resources. These awards are established by 42 USC 241 and 42 USC 288 and identified in the Catalogue of Federal Domestic Assistance (Attachment 11). 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.

The PHS 2271, Statement of Appointment, is used in the administration of institutional training grants and for appointees under career development program and other research training awards that authorize training for a specific number of individuals to be selected by the grantee

institution. When selection is made, the grantee submits the Statement of Appointment specifying the terms of the appointment. The PHS 2271 is used to activate all such appointments. Program policy requires that the Statement of Appointment be submitted before an individual receives funds under a training grant. (See Attachment 4.)

The Statement of Appointment is critical for NRSA program postdoctoral trainees who have a payback obligation in service or dollars, based on the length and amount of support, required by the National Research Act of 1974 (42 USC 288). The Statement of Appointment sets the terms of the trainee's obligation and is essential in developing an accurate and complete record of an individual's obligation to the U.S. Government. The permanent mailing address provides information critical to the agency's ability to contact the trainee after the award period.

The PHS 3734, Statement Relinquishing Interests and Rights in a PHS Research Grant, is used when an institution relinquishes a PHS grant award. (See Attachment 4.)

The Final Invention Statement, HHS 568, is submitted by grantees and reviewed by agency staff at the time of research project closeout to determine that the HHS patent reporting requirements are met. (See Attachment 4.)

The Interagency Edison Reporting System (iEdison) allows grantees and Federal agencies to meet statutory requirements for reporting inventions and patents that result from Federal funding agreements. iEdison is currently used by 21 Federal agencies. (35 USC 202 and 37 CFR 401.8) (See http://iEdison.gov)

Center grant programs, authorized by 42 USC 216, 42 USC 285, and 42 USC 300, are administered by several research institutes in accordance with regulations 42 CFR 52a.4. (Examples are in Attachment 7.)

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 the Agency missions in a highly competitive fiscal environment. In addition, information is used for program management, planning, budgeting, and appraisal of progress. Information collected is also used for reporting to Congress and the public.

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

a. by applicants to compete for funding for research, training, and related activities and to request access to agency resources;

b. by grantees to comply with administrative and policy requirements of terms and conditions of award;

c. by the Center for Scientific Review, Division of Receipt and Referral, to evaluate the basis of eligibility of the applicant and the completeness of the application, and to determine the

appropriate assignment of the application to a Scientific Review Group and PHS awarding component;

d.by Scientific Review Groups to evaluate the scientific and technical merit of the application, including the significance of the proposal, the approach, innovation, qualifications of the investigator(s), and scientific environment in which the proposed work would be conducted;

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

f. by the PHS awarding units to determine the fiscal benefits under the award, and to administer the award in compliance with public and program policies and all terms and conditions of award; and

g. by other agencies (DOE, NSF and USDA) to evaluate, review and potentially award SBIR/STTR applicants.

PHS 2590 - The Non-competing Grant Progress Report is used by the PHS awarding component to ascertain the progress made under an award; plans for the next year; compliance with applicable policies, procedures and terms; and funding for the next year under the project period.

PHS 2271 – The Statement of Appointment is used by PHS program staff as follows: (1) to determine if trainees appointed to the grant meet program eligibility requirements (e.g., education and citizenship requirements); (2) to ensure that the number of trainees do not exceed authorized levels; (3) to ensure that the appropriate stipend level is paid; and (4) to enable PHS to identify institutional recruitment and retention diversity equities. The Statement

of Appointment is also used by institutions to appoint individuals to career development and other research training programs, and can be used to collect information on graduate level research assistants engaged in research under regular research grants.

.

PHS 3734 – The Official Statement Relinquishing Interests and Rights in a PHS Research Grant is used primarily when a principal investigator on a research project transfers from one institution to another institution, and the original grantee institution relinquishes its rights to the grant ward.

HHS 568 – The Final Invention Statement is used by agency grants management staff at the time of research project closeout to determine that the Department's patent reporting requirements are met. The certification is not utilized as a basis for data compilation on patents; that purpose is served by the disclosures themselves.

The Interagency Edison Reporting System (iEdison) meets the Bayh-Dole Act requirements for reporting of inventions and patents that result from Federal funding agreements. (35 USC 202 and 37 CFR 401.8), and is currently used by approximately 21 Government agencies.

This request is for approval of the continued usage of these information collections as described above and modified pursuant to A.15 (Explanation for Program Changes or Adjustments) below.

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. The complete transition is dependent upon the ability of Grants.gov to fully accommodate electronic submission of all programs, including complex multi-project programs that require significant technical development to address application requirements.

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 398 data components and instructions to be used in conjunction with the SF424 (R&R) for electronic submission through Grants.gov. These 398 data components are presented in this package at Attachment 2.

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 398 data components.

Applications that have not yet transitioned to electronic submission continue to submit paper applications comprised solely of PHS 398 forms which are scanned and managed electronically upon receipt at NIH. The need for dual applications (total PHS 398 data arranged in paper form, and electronic packages that combine SF424 (R&R) data with agency-specific data) will continue 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 federal PHS agencies 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 close-out--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) E-SNAP supports the electronic submission of certain PHS 2590 progress reports under the Streamlined Noncompeting Award Process (SNAP). Electronic submission of SNAP progress reports eliminates paper submission of the original and 1 copy, and allows for electronic processing within the NIH. In FY06, over 14,600 eSNAPs were submitted. The number of institutions registered to use e-SNAP has grown from 70 in 2004 to over 2000 in 2007.

2) 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.

3) Progress Report Notification is 100% electronic. Grantees can electronically access all progress report due dates, and through the eRA Notification system principal investigators 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.

4) 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.

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. HHS 568

NIH is coordinating a cross-agency initiative concerning the HHS-568, Final Invention Statement and Certification. This effort has resulted in Federal-wide standard data elements for electronic summary reporting of inventions published in the Federal Register: October 30, 2002 (Volume 67, Number 210) Page 66178-66183. The Final Notice on this initiative is pending OMB Clearance. Once approved, these standard data elements will be incorporated into the iEdison system. This effort will ultimately result in the elimination of the HHS 568 and other similar Federal reporting forms used by other agencies, and consolidation these into a single interactive internet web form as part of the implementation of the Federal Financial Assistance Management Improvement Act of 1999 (Public Law 106-107).

d. User-friendly Forms

In those instances where paper applications are still in use, NIH uses fill-able Word forms, increasing efficiency while reducing burden on applicants. Forms are also available in PDF format.

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. Pre-populated forms are used when relevant pre-existing data is available, e.g., items 1-6 of the PHS 2590 are pre-populated for grantees and available through the eRA Commons. Since the E-SNAP system is an integral part of the eRA Commons, it fully utilizes previously collected information. Data collected on the Statement of Appointment (PHS 2271) is requested one time, when an individual is first appointed; if reappointed, the PHS 2271 need only be updated if necessary.

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

PHS 398: As noted in Section 3, NIH and other PHS agencies using the PHS 398 are in the process of transitioning from a paper-based PHS 398 to collecting application data using a combination of the Federal-wide SF424 (R&R) as well as agency-specific data components. This transition process is based on the initiative to coordinate application data requirements

across Federal agencies. When the transition is complete, the PHS 398 will be comprised only of those data elements that are unique to PHS programs and therefore are not part of the Federal-wide SF424 R&R data set (now the 398 component forms). All agency-specific data requirements are vetted within the Federal-wide R&R Working Group (representing 16 research agencies) to determine if other agencies have similar data needs.

SBIR/STTR Information Component: This specific component (included in Attachment 2), will also be used by the National Science Foundation, the Department of Energy, and the United States Department of Agriculture/Cooperative State Research, Education, and Extension Service, under this OMB approval. Therefore the burden hours for this component have been calculated separately, and the hours for these other agencies are included in this clearance request. This particular component is expected to become an official part of the SF424 (R&R) data set during its next OMB clearance process.

While all of the other PHS 398 specific components shown in this package have been shared with the agencies within the R&R Working Group, no other data components other than the SBIR/STTR Information Component can be used by other agencies at this time.

PHS 2590: The Federal-wide initiative for a standard Research Performance Progress Report will affect the PHS 2590; however the degree of impact is not known at this time.

HHS 568: As mentioned in 3.C above, the use of this form will eventually be subsumed under the new Federal-wide data elements for Summary Reporting of Inventions. Until that initiative is fully implemented, the HHS 568 will continue to be required.

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 and no longer require special accommodation. The SBIR/STTR mechanisms were the first mechanisms to transition to electronic submission . As noted in Section 4 there is one PHS 398 component form required of SBIR/STTR applicants that requests information specific to small business and other small entities. The PHS 2590 continuation application is used by the SBIR community, in lieu of a separate form for Phase II Small Business Innovation Research and Small Business Technology Transfer Programs (SBIR) noncompeting continuation support with simplified instructions.

6. Consequences of Collecting Information Less Frequently

The PHS 398 application is a one time data collection related to a request for assistance. The PHS 2590, non-competing grant progress report, is required by governing law and regulations. The PHS 2271, Statement of Appointment, is necessary to track and monitor individuals receiving support from NIH training programs and to comply with regulations regarding

payback provisions under NRSA. The PHS 3734 and HHS 568 are one time information collections.

7. Special Circumstances Relating to Guidelines of 5 CFR 1320.5

This request for deviation is for PHS 398 applications that are submitted on paper only (i.e., does not pertain to applications submitted electronically), which is approximately 20% of applications submitted at this time. Approval is requested to continue to receive an original and 5 copies of the application, a deviation from 5 CFR 1320.5 (c).

An additional 3 copies are required in order for the Center for Scientific Review to handle an annual workload of approximately 80,000 competing applications (paper and electronic, including NRSA Individual Fellowship Applications), in a dependable manner and within a rigorous time schedule. NIH is committed to completing the processing, review and funding of applications no later than 9 months after submission. This can only be accomplished if applicants submit an additional 3 copies. Further, the assurance that successful applicants can expect to initiate research 10 months from the NIH receipt date is critically importance to the dynamic nature of research, to the research community, and to funding agencies. These additional copies also ensure an accelerated processing timetable for the expedited review of AIDS research applications of 6 months.

8. Comments in Response to the FR Notice and Efforts to Consult Outside Agency

An announcement was placed in the Federal Register, July 24, 2007 (Volume 72, Number 141, Page 40313. No comments were received. Comments were also solicited from within NIH and from other PHS agency staff, and groups representing the scientific community and university administrators, thereby providing the grantee community an active voice.

Further, large regional meetings held twice each year with grants administrators from academic and research institutions provide an open forum for input and advice from the community. Participation in the Federal Demonstration Project (FDP) is another 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. Questions and comments from these meetings, as well as questions and comments from applicants throughout the year, are duly noted and utilized in modifying the PHS 398 and 2590, and other grant related information collections.

9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Release of information is fully explained in the applications PHS 398, 2590, 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 (IMPAC 2), Contract Information (DCIS), and Cooperative Agreement Information, HHS/NIH.

11. Justification for Sensitive Questions

The Personal Data Page (PHS 398 used only for paper submission) requests data that is encrypted and removed from the application by the agency 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.

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. This request is on the Personal Data Page and the PHS 2271, and provision of the partial Social Security Number is voluntary. No individual will be denied any right, benefit, or privilege provided by law because of refusal to disclose his or her Social Security Number.

The PHS requests diversity data on the PHS 2271 Statement of Appointment in order to obtain statistical information on the participation of individuals from diverse groups, and identify inequities in terms of recruitment and retention based on race, ethnicity, disability and/or disadvantaged background. Provision of the information is voluntary and retained in accordance with and protected by the Privacy Act of 1974. All analyses utilizing the data reports aggregate statistical findings only and do not identify individuals.

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 remains constant at 40 hours. However, for those mechanisms that have transitioned to electronic submission (80% of mechanisms), it is estimated that approximately 38% of the 40 hour burden has shifted to the SF424 (R&R), and the remaining estimated average burden for the PHS 398 component forms is 25 hours. The estimated average time to complete the PHS 2590 remains at 15 hours. The estimated average time to complete the HHS 568 is .08 hours. The estimated average burden for the PHS 2271 is .33 hours for new appointments and .17 minutes for reappointments and amendments (thus an average time of .25 hours is used for purposes of this clearance). The estimated average time to complete the PHS 3734 is .15 hours.

Since each of these forms serves a different purpose, the number of respondents differs depending on the form used. The average number of respondents per year is estimated at 69,500 for the PHS 398 (paper and electronic); 37,000 for the PHS 2590; 15,500 for the PHS 2271; 17,500 for the HHS 568; and 700 for the PHS 3734. In addition, certain applications require letters, e.g., applicants requesting $500,000 or more in direct costs for any year are required by NIH Policy to include a cover letter with the application, and applicants for Career Development Awards (CDAs) are required to include three separate letters of reference, and a letter of support from the applicant's Department head. The numbers of letters submitted are estimated to be: 335 for applicants requesting $500,000; 10,200 letters of reference for CDAs; and 3,400 Department head letters for CDAs. The average estimated burden for each letters is .50 hours.

The burden for use of the SBIR/STTR information component for the National Science Foundation, Department of Energy, and U.S. Department of Agriculture/Cooperative State Research, Education and Extension Services is calculated separately using burden hours and numbers of respondents provided by those agencies.

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

Cost to PHS 398 respondents:	$68,100,000
Cost to PHS 2590 respondents:	$19,425,000

Cost to SBIR/STTR (NSF, DOE, USDA):	$89,355
Costs to PHS 2271 respondents:	$135,625
Costs to HHS 568 respondents:	$51,030
Costs to PHS 3734 respondents:	$3675
Other annualized costs (letters, iEdison):	$296,345
Total:	$88,111,030

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.

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).

15. Explanation for Program Changes or Adjustments

The difference listed in the OMB 83-I Form Item 13 for burden totals, is an increase of 42,820. 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 Changes to Instructions is Attachment 8. Data collection changes are as follows:

Form/Format Pages	Change	Rationale
398 Form Page 1 (face page)	Delete item 5a (IACUC approval date)	Information collected under Just-in-Time.
398 Form Page 2	Addition of DUNS and Congressional District fields for performance sites.	Required by the Federal Financial Accountability and Transparency Act (FFATA).
398/2590 Performance Site Format Page	New format page for additional performance site information.	Required by FFATA.
398 Checklist Form Page and PHS 398 Checklist (electronic)	Add Disclosure/Permission statement.	Allow NIH to share information with potential 3rd party collaborators, sponsors, etc.
398 Modular Budget Format Page	Deleted from paper 398 application.	Necessary for electronic submissions only.
Key Personnel Report Format Page	Delete date of birth column.	Data not used.
CDA Substitute Table of Contents	Add checkbox for non-citizen with temporary visa status.	Accommodate requirements for new program.
Institutional Training Grant Forms (3)	Titles of forms changed.	Acknowledge that program includes non-NRSA mechanisms.
Institutional Training Grant Data Table Format Pages	Fillable format pages and samples of completed tables provided.	Provide structure for and promote consistency in data tables.
2590 Form Page 1	Delete field for Full IRB or Expedited Review.	Information not necessary.
2590 Form Page 7	Delete date of birth column.	Data not used.
2590 Trainee Diversity Report	New, replace use of Human Subject Enrollment Report.	Less confusing to applicant.
2590 Summary of Trainees, additional form page 5	Deleted.	Information provided in Institutional Training Grant Data Table.
2271 Stmt of Appointment	New checkbox for non-citizen with temporary visa status;	Accommodate requirements for new program.

	additional field for country of citizenship if non-US citizen.	
2271 Stmt of Appointment	Add disability and disadvantaged background question.	Implement NIH diversity recruitment and retention policy.
2271 Stmt of Appointment	Delete month and year educational institution attended.	Not necessary.
2271 Stmt of Appointment	Include option of "no degree sought."	Not all appointees seeking degree.
2271 Stmt of Appointment	Include salary and other compensation in Stipend field.	Accommodate broader use of form.
2271 Stmt of Appointment	Delete fields for PD's school and department	Information not necessary.
HHS 568	Delete requirement for PI signature.	Not necessary.
SBIR/STTR	Use by NSF, DOE, and USDA.	Temporary measure until SF424 OMB clearance includes SBIR/STTR forms.

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.

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

The OMB Number and expiration date are displayed on the forms.

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.

Supporting Statement Attachments (electronic)

Attachment 1 - 398 Forms
Attachment 2 - 398 Components and SBIR/STTR Component Forms
Attachment 3 - 2590 Forms
Attachment 4 - 2271, 568 and 3734 Forms and Instructions
Attachment 5 - 398 Instructions
Attachment 6 - 2590 Instructions
Attachment 7 - Examples of Program Guidelines

- 2590 Supplemental Instructions
- BTRR Guidelines
- CRC APR Instructions
- GCRC Guidelines
- IDEA Program Guidelines
- RCMI APR Instructions
- RCMI Clinical Research
- RCMI Program Guidelines

Attachment 8 - Summary Table of Changes to Instructions
Attachment 9 - CFDA List