Supporting Statement A

Research and Research Training Grant Applications and Related Forms, NIH

February 27, 2009

Name: Carol Wigglesworth
Address: 6705 Rockledge Drive, Bethesda, MD 20892-7974
Telephone: 301-435-0931
Fax: 301-435-3059
Email: wigglesc@od.nih.gov

Table of contents

List of Attachments

SUPPORTING STATEMENT

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 to request access to agency sponsored resources. Several PHS 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. Several offices within the HHS Office of the Secretary (OS) are serviced by NIH for grant programs and also use this application. 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 11/2010. This out-of-cycle submission is the result of (1) programmatic peer review changes that impact applicant instructions and shorten page limits, and (2) the NIH workforce initiative, long-standing analytical need for data required by the PHS Act, and related reporting requirements of the NIH Reform Act of 2006 (P.L.109-482).

Also included under 0925-0001 are:

- PHS 2590: Non-Competing Continuation Progress Report
- PHS 2271: Statement of Appointment
- PHS 3734: Official Statement Relinquishing Interest/Rights in a PHS Research Grant
- HHS 568: Final Invention Statement and Certification

- Interagency Edison Reporting System
- Supplemental Instructions for specialized NIH programs, including Center Grant Programs, authorized by 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.

This request is for approval of the continued usage of these information collections modified pursuant to Section A.15 Explanation for Program Changes or Adjustments.

Justification

1. Circumstances Making the Collection of Information Necessary

The PHS 398 enables public and private organizations to request funds or access to other benefits from the PHS Agencies listed in the previous section, and HHS/OS offices serviced by NIH. 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, but most frequently to request financial support through the assistance mechanism for traditional investigator-initiated research projects. Some specialized programs use the application to request access to databases and other PHS resources.

NIH and other PHS Agencies are transitioning to the Federal-wide application data set, SF424 (R&R), which is submitted electronically through Grants.gov (see Section 3. Use of Information Technology and Burden Reduction). During the transition period which will last several more years, there is 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 1), the entire set of PHS 398 instructions (Attachment 2), and the PHS 398 component forms and agency specific instructions used in combination with the Federal-wide SF424 (R&R) (Attachment 3). Use of the PHS 398 paper application diminishes as programs transition to electronic submission. At this time approximately 83% of applications have transitioned to electronic submission and use the SF424 (R&R) and PHS 398 component forms.

The Non-Competing Continuation Progress Report (PHS 2590) is used to request funds for subsequent budget periods within an approved project 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, the recommended level of support, progress reported, and the availability of funds. (See Attachments 4 for PHS 2590 forms that are modified since the last OMB approval, and Attachment 5 for the entire set of PHS 2590 instructions.)

In addition to the Research Project Grant, the PHS uses these applications and progress reports 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 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 6). 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, documents grantee appointments of individuals under Institutional Training Awards, including the Ruth L. Kirschstein NRSA and other specialized research training programs. Program policy requires that the 2271 be submitted before an individual receives funds under a training grant, and PHS uses the form to activate appointments. The 2271 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 2271 defines the terms of the trainee's obligation and is essential in documenting an individual's obligation to the U.S. Government. The permanent mailing address requested on the form is especially important 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 serves as the official record of grantee relinquishment of a PHS grant award.

The Final Invention Statement, HHS 568, documents that the HHS patent reporting requirements are met. The Interagency Edison Reporting System (http://iEdison.gov) 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).

There are no changes proposed to the PHS 2271, HHS 568 and PHS 3734, or iEdison.

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. There are no changes to program guidelines.

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 has enabled PHS agencies to continue to receive research and training applications from the research community, to fund new and noncompeting awards, monitor awards, and effectively close-out awards at the end of the project period.

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; and

vii. by the PHS awarding units to collect workforce information required by P.L. 109-482.

PHS 2590 - The Non-competing Continuation Progress Report is used by the PHS awarding components to ascertain progress under an award, plans for the ensuing year, compliance with applicable policies, procedures and terms, collect workforce tracking data, and determine funding for the ensuing year under the project period.

PHS 2271 – The Statement of Appointment is used by PHS program staff to: i.) determine if trainees meet program eligibility (education and citizenship) requirements; ii.) ensure that the number of trainees do not exceed authorized levels; iii.) ensure that the appropriate stipend level is paid; and iv.) identify any institutional recruitment and retention diversity inequities. The 2271 is also used by institutions to appoint individuals to career development and other

research training programs, and may be used by NIH to collect information on graduate research assistants engaged in research under regular research grants.

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

HHS 568 – The Final Invention Statement is required of grantees at the time of award close-out to determine that the Department's patent reporting requirements were 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.

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. Complete transition of all programs to *Grants.gov Apply* is dependent upon *Grants.gov* ability to accommodate complex multi-project programs that require significant technical development to address application requirements. To date, 83% of grant programs have successfully transitioned to electronic submission.

Another Federal-wide streamlining initiative affecting applications is 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.

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) (see Attachment 3). 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.

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 a significant commitment to improve administrative operations through information technologies and reengineering of business processes. eRA also 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), eliminating paper submissions of the original and 1 copy and allowing electronic agency processing. The number of institutions registered to use e-SNAP has grown from 70 in 2004 to 2900 in 2008. In FY08, over 23,500 eSNAPs were submitted. .

2) 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.

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 also provides pre-populated progress report face pages that utilize existing data, further reducing applicant burden.

4) Other electronic notifications include e-mails at various stages of the application process: receipt, assignment, change of assignment, review outcome, and summary statement availability; these notifications eliminated the previous paper processes.

5) Personal Profile provides principal investigators and reviewers with a secure electronic environment to maintain information concerning degrees, publications, affiliations with institutions, and other professional information in the NIH system, which associates profiles with NIH grant awards. The majority of the data collected is a one-time collection; however institutional affiliations and publications are updated as necessary. This data is used by the agencies to evaluate demographic information, determine eligibility for programs, and for workforce analysis. 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, 0925-0002, and 4040-0001. (See Attachment 7 for the data elements of the eRA Commons Personal Profile.)

6)xTrain supports the electronic submission of the data collected on the PHS 2271.

7) Other eRA Commons functionality currently in production include electronic submission of post-award reporting: Financial Status Reports (SF 269), close-out documents, Financial Conflict of Interest notifications, and no-cost extension notifications.

c. HHS 568

NIH is coordinating a cross-agency initiative in accord with the Federal Financial Assistance Management Improvement Act of 1999 (P.L. 106-107), concerning the

HHS-568, Final Invention Statement and Certification. This effort has resulted in OMB established standard data elements for iEdison (73 FR 59680) that will eventually be incorporated into the iEdison system and obviate the need for the HHS 568 Final Invention Statement and other similar Federal reporting forms used by other agencies. Thus, the HHS 568 will eventually no longer be included in this information collection; the OMB established data elements will be approved under a separate number.

d. User-friendly Forms

Where paper applications and forms 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 are not 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 in eSNAP. Data collected on the PHS 2271 is requested one time (upon appointment); upon reappointed the information is updated only as necessary.

There are a number of ongoing Federal-wide initiatives in which NIH actively participates that will impact forms and datasets:

PHS 398: 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 be comprised 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. At this time, other agencies do not have a need for the 398 specific data components. The Personal Data form page, formerly part of the PHS 398, is eliminated; the data previously collected on the Personal Data form page is now part of the eRA Commons Person Profile dataset.

PHS 2590: The Federal-wide initiative for a standard Research Performance Progress Report will affect the PHS 2590; 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.

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 Small Business Innovative Research and Small Business Technology Transfer (SBIR/STTR) grants were the first to transition to electronic submission. The PHS 398 component form previously required of SBIR/STTR applicants is now part of the grants.gov SF424(R&R) burden (OMB Approval 4040-0001), and no longer part of OMB Approval 0925-0001. The PHS 2590, with simplified

instructions, is used by the SBIR community in lieu of a separate form for Phase II SBIR/STTR noncompeting continuation support.

6. Consequences of Collecting Information Less Frequently

With the exception of the PHS 2590 which is required annually by governing law and regulation, all other forms represent one time information collections. The PHS 2590 is occasionally used for interim reporting when required by a particular program, of a particular grantee, or by law.

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 17% 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 80,000 competing applications (paper and electronic) in a dependable manner and within a rigorous time schedule. Assurance that successful applicants can expect to initiate research 10 months from the NIH receipt date is critically important to the dynamic nature of research, to the research community, and to funding agencies, and 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.

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

An announcement was placed in the Federal Register, December 10, 2008 (73 FR 75121). No written comments were received. However, changes resulting from the NIH Enhancing Peer Review Initiative are the result of extensive consultation with NIH internal and external communities (http://enhancing-peer-review.nih.gov/index.html). This consultation continued through the December 5, 2008 public meeting of the Advisory Committee to the Director [of NIH], where the ACD unanimously rejected a plan to provide applicants proposing human subjects research with an additional 8 pages for the Research Strategy, emphasizing fairness to applicants. That provision, which was included in the PHS 398 at the time of the 12/10/2008 FR request for comment, was removed from this submission in light of the ACD's concerns.

Other consultations occur regularly at NIH Regional Seminars on Program Funding and Grants Administration held twice each year. Participation in the Federal Demonstration Project (FDP) 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, post-award monitoring, and other administrative aspects of the PHS programs. Questions, comments and discussions from these meetings and throughout the year are duly noted and considered when modifying 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

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. Release of information is fully explained in all grant related information collections.

11. Justification for Sensitive Questions

The eRA Commons Personal Profile and the PHS 2271 request 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 confidential data are maintained in a Privacy Act record system (09-25-0036).

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 is reduced (from 40 hours to 35 hours) in light of the reduced page limit allowance (see Attachment 8, Summary Table of Noteworthy Changes to Instructions). For those activity codes that have transitioned to electronic submission (83% of all applications),

NIH continues to estimate that approximately 38% of the burden has shifted to the SF424 (R&R). The remaining estimated average burden for the PHS 398 component forms is reduced by 12% (from 25 hours to 22 hours) in accord with the reduced page limit. The estimated average time to complete: the PHS 2590 remains at 15 hours, the HHS 568 remains at .08 hours, the PHS 3734 remains at .15 hours, and the PHS 2271 remains at .33 hours for new appointments and .17 minutes for reappointments and amendments (thus an average time of .25 hours for the PHS 2271 is used for purposes of this clearance).

Because 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., 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. The numbers of letters submitted are estimated to be: 335 for applicants requesting $500,000 or more; 10,200 letters of reference for CDAs; and 3,400 Department head letters for CDAs. The average estimated burden for each letter is .50 hours.

The burden previously provided 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 has been removed (See Section 5. Impact on Small Business or other Small Entities.)

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:	$58,890,825
Cost to PHS 2590 respondents:	$19,425,000
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:	$78,802,500

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 awards. The extramural research program is a $22,400,000,000 enterprise (80% of the total NIH budget appropriation).

15. Explanation for Program Changes or Adjustments

NIH conducted an extensive formal and in-depth review of the NIH peer review system resulting in a number of selected recommendations and key actions that are presently undergoing a phased implementation. A major recommendation involves the shortening and restructuring of the research plan of the PHS 398 grant application, which NIH will implement for applications submitted in January 2010 and beyond, allowing the change to be effected for a full Fiscal Year (applications submitted 1/2010 and beyond are funded in FY2011). The other significant factor reflected in this out-of-cycle submission is the NIH workforce initiative, mandated by the NIH Reform Act of 2006 and requiring collection of identifying and demographic information and reporting on those with a postdoctoral role who serve as research assistants or associates on research grants. This data will be collected through the eRA Commons Personal Profile and the PHS 2590. In addition, the Senior/Key Personnel Report, part of the PHS 398 and the PHS 2590, is replaced with an All Personnel Report to be used for reporting all personnel associated with a project for a period of one month or more. This will clarify, simplify and improve this data collection, and, coupled with the eRA Commons Personal Profile, create a reliable linkage of those with a postdoctoral role to research projects. The 398 Personal Data Form Page is eliminated; the information previously collected on this page is now part of the eRA Commons Personal Profile.

These changes are reflected in the difference in burden totals, a decrease of $9,308,530 (10.5%). The decrease is attributable to three factors: 1) a 3% increase in the number of applications submitted electronically (now 83%); 2) reduced page limits for the Research

Strategy (from 25 pages to 12 pages for most applicants; from 12 pages to 6 for others); and 3) transfer of the SBIR/STTR burden for NIH, NSF, DOE and USDA to the grants.gov SF 424 (R&R) (OMB Number 4040-0001). A Summary Table of Noteworthy Changes to Instructions is Attachment 8. Form page changes are as follows:

Form/Format Pages	Change	Rationale
398 Form Page 1: (Face Page)	"new investigator" yes/no box eliminated	New Investigator status to be determined electronically in eRA Commons Personal Profile, through previous association as PI on past grant awards
398 Form Page 3: Table of Contents	Replace former components of Research Plan 3, 4, and 5 with single Research Strategy component	Alignment of application instructions with peer review criteria pursuant to Enhancing Peer Review Initiative
Personal Data Form Page	Eliminated	Information collected in the eRA Commons Personal Profile
All Personnel Report Format Page	Rename form; add column to collect Commons ID for all personnel involved on the grant for one month or more, and month/year of birth.	Address longstanding analytical need for data required by PHS Act, and reporting requirement mandated by NIH Reform Act of 2006.
Biosketch Format Page	Request personal statement, limit number of publications to 15, capture residency field of study, and month/year of degree/residency completion.	Personal statement and publications limit are pursuant to Enhancing Peer Review Initiative; other changes represent need for NIH to capture information on terminal degree and mo/year of residency training to evaluate new investigator policies and impact on workforce.
PHS 398 CDA Supplemental Component for Electronic Submission	Replace former paper CDA Substitute Form Page 3, and replace former components of Research Plan 3, 4, and 5 with single Research Strategy component	Transition of CDA applications to electronic submission, and alignment of application instructions with peer review criteria pursuant to Enhancing Peer Review Initiative
PHS 398 Research Plan, Component for electronic submission with SF 424(R&R)	Replace former components of Research Plan 3, 4, and 5 with single Research Strategy component	Alignment of application instructions with peer review criteria pursuant to Enhancing Peer Review Initiative
PHS 2590	Renamed form; add column to	Address longstanding analytical

All Personnel Report Format Page	collect Commons ID for all personnel involved on the grant for one month or more, and month/year of birth	need for data required by the PHS Act, and reporting requirement mandated by NIH Reform Act of 2006.

16. Plans for Tabulation and Publication and Project Time Schedule

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

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

The OMB number and expiration date are displayed on the paper forms. The OMB number is displayed on all forms developed by Grants.gov for electronic submission; the expiration date is not displayed in order to obviate the need for Grants.gov forms development for date changes only. The expiration date is noted in all application instructions.

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.