Supporting Statement A

PHS Research Performance Progress Report and Other Post-award Reporting
0925-0002

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Table of contents

SUPPORTING STATEMENT

Overview

National Institutes of Health and other Public Health Service grantees are required to submit interim and final progress reports and other post-award documents associated with the monitoring, oversight, and closeout of an award. This submission represents a consolidation of post-award reporting requirements into a revised data collection under the Paperwork Reduction Act, referred to here as 0925-0002 (previously known as Individual Ruth L. Kirschstein National Research Service Award Applications and Related Forms). The collection includes post-award reporting requirements previously collected under 0925-0001 and 0925-0002. Application and other pre-award related forms are similarly consolidated and concurrently submitted under 0925-0001.

This reconfiguration represents a logical consolidation of forms for the following reasons:

- The new Research Performance Progress Report (RPPR) will replace two existing forms that previously were approved under different collections (PHS 2590 approved under 0925-0001, and 416-9 approved under 0925-0002). Maintenance of the existing progress report collection is necessary for a limited period and solely to allow sufficient time to fully transition to the RPPR. Although approval of dual interim reporting processes is necessary during the transition to full use of the RPPR, only one information collection will be utilized for any given award (either the RPPR or the PHS2590/416-9). Once the RPPR is fully implemented the PHS 2590 and 416-9 will no longer be used.
- Grouping pre- and post-award reporting requirements is a logical configuration reflecting typical functional division of responsibilities, authorities and business processes in the agencies as well as

at grantee institutions. For example, at the agency pre-award activities are governed by Peer Review regulations and are the responsibility of Scientific Review Officers and peer review committees and advisory councils, while post-award activities are managed solely by Grants Management Officers and Program Officials. Responsibilities at grantee institutions are correspondingly usually divided into pre-and post-award activities.

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

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

Several PHS Agencies in addition to the NIH utilize the RPPR and other forms under 0925-0002: Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA). NRSA specific forms (PHS 416-7, 2271 and 6031-1) are utilized only by agencies with NSRA authority (NIH, AHRQ, and the Health Research and Services Administration). The Indian Health Service utilizes the PHS 2590 for one program.

The information collections included in this submission are:

1. RPPR – Research Performance Progress Report
2. PHS 2590: Non-Competing Continuation Progress Report, and PHS 416-9: Individual Fellowship Progress Report for Continuation Support

3. PHS 416-7: Termination Notice for National Research Service Award
4. PHS 2271: Statement of Appointment
5. PHS 6031-1: Annual Payback Activities Certification for National Research Service Award
6. HHS 568: Final Invention Statement and Certification
7. Final Progress Report Instructions
8. Interagency Edison Reporting System (iEdison)
9. PHS 3734: Official Statement Relinquishing Interest and Rights in a PHS Research Grant

Justification

1. Circumstances Making the Collection of Information Necessary

NIH and other PHS agencies are authorized to issue discretionary awards under 42 USC 241; 42 USC 216; 42 USC 285: 42 USC 285(j); 42 USC 286: 42 USC 300;42 USC 288; and 31 USC 6305, and to collect information as authorized in accordance with 42 CFR Part 52, 42 CFR 66.204, and 45 CFR 74. NRSA were established under statutory authorities contained in the PHS Act as amended at 42 USC 288. Information collection requirements specified in the regulations governing the NRSA programs include 42 CFR 66.104(b), 66.105(b) and 66.110. Awards are identified in the Catalogue of Federal Domestic Assistance (Attachment 2).

RPPR, PHS 2590 and 416-9: PHS agencies utilize a project period system to fund awards, i.e., projects that will continue for more than one year are programmatically approved for support in their entirety but generally funded in annual budget period increments. To receive funding of each subsequent budget period grantees are required to submit an interim progress report which is reviewed by agency program and administrative officials within the framework of the approved research project, the recommended level of

support, progress reported, and the availability of funds. The PHS 2590 Non-Competing Continuation Progress Report (see Attachment 3 for forms and Attachment 4 for instructions) is currently used for interim progress reporting of all PHS awards except NRSA Fellowships; the PHS 416-9, Individual Fellowship Progress Report for Continuation Support (see Attachment 5 for forms and Attachment 6 for instructions) is currently used for interim progress reporting for all NRSA Fellowship awards authorized under the PHS Act. Implementation of the RPPR, in accord with the 4/21/2010 memo from OMB/OSTP "Policy on Research Performance Progress Report" establishing a uniform format for use in submission of required annual or other interim performance reporting on grant and cooperative agreement awards, will ultimately replace the PHS 2590 and 416-9. The DHHS/NIH (and Other PHS Agencies) Implementation Plan, updated January 2012, is available on the RPPR website, and describes a phased implementation beginning in the fall of 2012. The RPPR screen shots are provided at Attachment 7 and RPPR Instruction Guide at Attachment 8. As indicated above, approval of existing progress reports (PHS 2590 and 416-9) is for a limited period and solely to allow sufficient time to fully transition to the RPPR.

The RPPR will be used for interim progress reports for all NIH programs including but not limited to: research project grants, NRSA and other institutional training grants, NRSA Fellowships, career development awards, SBIR/STTR awards, program project and center grants, conference grants, cancer center support grants, biotechnology resource grants, and academic research enhancement awards.

Other post-award information collections are necessary as follows:

PHS 416-7 – Termination Notice is the official record of training under NRSA and other institutional research training programs, individual NRSA and other individual fellowship programs, and, where

applicable, establishes an individual's payback obligation (see Attachment 9 for PHS 416-7 instructions and form).

PHS 2271 - Statement of Appointment documents grantee appointments of individuals under institutional training awards, including 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. (See Attachment 10 for instructions and form.)

PHS 6031-1 –NRSA Annual Payback Activities Certification documents payback service and acceptance by PHS (see Attachment 11 for instructions and form).

HHS 568 - Final Invention and Certification Statement documents compliance with HHS invention/patent reporting requirements (see Attachment 12 for instructions and form).

Final Progress Report – Documents activities performed under an award, including publications as a result of the award, resources developed, human subject enrollment data, etc., in accord with closeout procedures defined in 42 CFR 74.71 (see Attachment 13 for PHS Final Progress Report Instructions).

iEdison – Necessitated by the Bayh-Dole Act invention and patent reporting requirements (35 USC 202 and 37 CFR 401) (see iEdison).

PHS 3734 – Statement Relinquishing Interests and Rights in a PHS Research Grant, most commonly used when an award is transferred from one grantee institution to another, serves as the official record of grantee relinquishment of a PHS award (see Attachment 14 for instructions and form.)

2. Purpose and Use of the Information Collection

RPPR, PHS 2590 and 416-9 - Information collected as part of interim progress reports is used by agency staff to: (a) monitor federal awards and ensure compliance with applicable terms and conditions of award, regulations, policies and procedures, (b) evaluate progress in accord with goals, aims and objectives set forth in competing applications, (c) evaluate grantee plans for the next budget period and any significant changes, (d) collect workforce tracking data as required by P.L. 109-482, (e) manage scientific programs, (f) plan future scientific initiatives, (g) determine funding for the next budget segment, and (h) report to Congress, the public and other Federal agencies.

PHS 416-7 and PHS 6031-1 - Information is used by PHS to close-out records of NRSA and other training award recipients, and to administer the legislated payback requirements of the NRSA program. Specifically, the 416-7 Termination Notice serves as a final progress report for NRSA Fellowships and other individual fellowship award recipients, documents support received by individuals on institutional NRSA and other training awards, and, where applicable, establishes an individual's payback obligation. The 6031-1 Annual Payback Activities Certification documents payback service and PHS acceptance of that service.

PHS 2271 - The Statement of Appointment is used by PHS staff to: 1) determine if trainees meet program eligibility (education and citizenship) requirements; 2) ensure that the number of trainees do not exceed authorized levels; 3) ensure that the appropriate stipend level is paid; and 4) 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.

HHS 568 - Final Invention and Certification Statement documents grantee compliance with the HHS invention/patent reporting requirements and is required as part of agency close-out procedures.

Final Progress Report – Required as part of 45 CFR 74.10 and agency close-out procedures, the Final Progress Report documents the grantee's activities under the award, finalizes reporting of publications, human subjects inclusion, research resources, and any other specific terms and conditions of award.

The Interagency Edison Reporting System - iEdison provides a mechanism to comply with the Bayh-Dole Act requirements for reporting of inventions and patents that result from Federal funding agreements and is currently used by over 29 Government agencies.

PHS 3734 - 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.

3. Use of Information Technology and Burden Reduction

a. Use of the eRA Commons and Data Dictionary for Progress Reports - The format of the RPPR provides a standardized interface for reporting to be adopted by all agencies supporting research or research related activities. PHS will implement the RPPR in NIH's electronic research administration (eRA) system through the eRA Commons and will utilize the standardized RPPR Data Dictionary, and eventually the RPPR XML schema, as developed by the research agencies. With full implementation of the electronic RPPR, all paper progress reports to NIH, FDA, AHRQ and CDC will be eliminated.

eRA Commons allows for pre-population of all RPPR Cover Page data elements from NIH IMPACII systems, automated reminders alerting grantees when a progress report is due, automated late notices, and automated notifications to NIH grantees if publications are reported that are not in compliance with the NIH Public Access Policy. The Commons includes an interface with the National Library of Medicine's My NCBI (National Center for Biotechonology Information) that pre-populates the progress report with the user's scientific publications and allows for easy affiliation of publications with award. Other data elements, such as project-performance sites, are pre-populated from the competing application and may be modified in the progress report. Goals of the project, personnel, and other data elements are pre-populated after the initial progress report, and may be modified in subsequent reports. The Commons also allows for electronic routing of the progress report within the grantee institution (e.g. between Principal Investigator or designee, and Authorized Organization Representative), and electronic submission to the agency.

As necessary, award programs will continue to utilize the PHS 2590 and 416-9 until the transition to RPPR is completed, however, the majority of NIH awards are issued under the Streamlined Noncompeting Award Process (SNAP) and already submit progress reports electronically (see b. Continued use of eSNAP pending transition to RPPR below). These same awards, plus the cohort of awards that are NRSA Fellowships, are included in the first phase of RPPR implementation, scheduled for the fall of 2012. Thus, beginning in the fall of 2012 over 80 % of awards are expected to use the RPPR.

b. Continued use of e-SNAP pending transition to RPPR - Pending transition to the RPPR module in the fall of 2012, the eRA Commons eSNAP Module will continue to support the electronic submission of PHS 2590 progress reports for SNAP awards. Use of e-SNAP was mandated for all SNAP progress reports for FY2011 awards.

c. Electronic submission of 2271 and 416-7 via xTrain - xTrain supports the electronic submission of PHS 2271 data and 416-7 termination notices. It efficiently reduces time spent by applicants preparing and submitting these forms. Use of xTrain is now mandatory for most NIH institutional training awards, and its use will continue expanding to other NIH research education and institutional career development awards.

d. HHS 568 and iEdison - 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 establishing 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 and Certification Statement and other similar Federal reporting forms used by other agencies. In the meantime, NIH grantees are strongly encouraged to submit the HHS 568 electronically through the NIH Central Closeout Center.

e. Final Progress Report – NIH grantees are strongly encouraged to submit the Final Progress Report electronically through the NIH Central Closeout Center (see Grants Policy Statement (GPS), 8.6).

f. Relinquishing Statement PHS 3734 – NIH is piloting an eRA Change of Institution module that allows grantees to electronically complete and submit the PHS 3734 Relinquishing Statement.

4. Efforts to Identify Duplication and Use of Similar Information

Information similar to that specified under this OMB collection does not exist elsewhere; thus there is no other method for collection. Interim progress reports address findings, publications, personnel, changes,

and the status of activities such as research with human subjects and select agents, and compliance with legal requirements, policies and other terms of award. Where relevant pre-existing data is available from NIH systems the data is pre-populated for the grantee. Likewise, information provided in NRSA termination notices, payback agreement and activities certification, final progress reports and invention reporting and certification, are unavailable elsewhere.

5. Impact on Small Business or other Small Entities

The procedures for small businesses and other small entities are the same as for other grantees. Interim progress reporting of SBIR/STTR awards, currently under the PHS 2590, will transition to the RPPR with minor adjustments as appropriate (e.g., the RPPR technology transfer component will be adopted solely for SBIR/STTR awardees). A SBIR/STTR Phase II Final Progress Report format is provided to facilitate NIH reporting to Congress and the Small Business Administration (SBA) on the commercialization activities of NIH SBIR/STR awards. The impact on small business or other small entities is anticipated to be negligible.

6. Consequences of Collecting Information Less Frequently

Information is collected at crucial points in the post-award process: interim progress reporting is required annually to fund subsequent budget periods, NRSA forms are collected at the end of training and, when applicable, document payback activities in accord with legislatively mandated timelines, and close-out documents are required by agencies within 90 days of the end of a project. It is not possible to collect this information less frequently.

7. Special Circumstances Relating to Guidelines of 5 CFR 1320.5

Not Applicable.

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

An announcement was placed in the Federal Register, March 5, 2012 (77 FR 13131), and a correction published March 26, 2012 (77 FR 17488). One public comment was received which asked clarification about new reporting burdens. It was noted in follow-up that NIH has seen a 21% increase in competing applications since the last clearance which has resulted in an increase in the burden hours. We are also transitioning to the Research Performance Progress Report (RPPR) as mandated by OMB.

NIH actively participated in the development of the RPPR Final Format through the Research Business Models Subcommittee of the Committee on Science, National Science and Technology Council. The draft RPPR was published for comment in the Federal Register (72 FR 63629); 347 comments were received and considered in the final version of the RPPR promulgated by the OMB/OSTP Policy letter.

Other consultations occur regularly at NIH Regional Seminars on Program Funding and Grants Administration twice each year. Participation in the Federal Demonstration Project, and meetings of professional organizations such as the National Council of University Research Administrators, Society for Research Administrators, and the Council on Government Relations, also provide an avenue of productive communication with the grantee research community. These meetings present opportunities 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.

9. Explanation of Any Payment or Gift to Respondents

Not Applicable.

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 II), Contract Information (DCIS), and Cooperative Agreement Information, HHS/NIH. The SORN 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.

11. Justification for Sensitive Questions

For many years NIH collected the last four digits of the social security number (SSN) on the [former] Senior/Key Personnel Report in the PHS 2590. In 2009, OMB approved replacing the Senior/Key Personnel Report with an All Personnel Report used for reporting all personnel associated with a project for a period of one month or more, and the collection of the month/year of birth on the Report to assist with identifying individuals. These two data elements have vastly improved the quality of the data needed for reporting on the size and characteristics of the biomedical research workforce, as called for by Congress, scientific leaders, and committees of the National Academy of Sciences. The ability to distinguish individuals also allows NIH to track the career paths of its trainees and fellows, and assess the outcomes of research training programs.

Under all circumstances, the provision of the abbreviated SSN and month/year of birth are voluntary and no individual is denied any right, benefit, or privilege provided by law because of refusal to disclose the

information. The data is not provided to peer review or Advisory committees. All analyses 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

The estimated average time to complete the PHS 2590 or 416-9 remains at 15 hours, and it is estimated that completion of the RPPR will take the same amount of time. Since grantees will complete either the PHS 2590/416-9 or the RPPR, the burden is calculated for either form, not both. The estimated average time to complete the 416-7 remains at 30 minutes, the 2271 remains at 15 minutes, and the 6031-1 remains at 20 minutes. The estimated time to complete the HHS 568 remains at 5 minutes, and time to complete iEdison remains at 15 minutes. The Final Progress Report, previously incorporated into the PHS 2590 instructions and burden calculation, is now provided and calculated separately. The Final Progress Report is a brief document and the burden estimate is calculated as 1 hour. The time to complete the 3734 remains at 6 minutes. 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.

Estimates of Hour Burden				
Information Collection Number or Title	**Number of Respondents**	**Frequency of Response**	**Average Time (hrs) Per Response**	**Annual Burden Hours**
RPPR (or 2590 or 416-9)	40,569	1	15	608,535
PHS 416-7	3,371	1	30/60	1,686
PHS 2271	15,500	1	15/60	3,875
PHS 6031-1	1,600	1	20/60	533
HHS 568	22,681	1	5/60	1,814
Final Progress Report	22,681	1	1	22,681
iEdison	6,000	1	15/60	1,500
PHS 3734	584	1	6/60	58

Estimates of Hour Burden				
Information Collection Number or Title	**Number of Respondents**	**Frequency of Response**	**Average Time (hrs) Per Response**	**Annual Burden Hours**
TOTALS	**112,986**		**5.6**	**640,677**

Annualized Cost to Respondents					
Information Collection Number or Title	**Number of Respondents**	**Frequency of Response**	**Average Time (hrs) Per Response**	**Hourly Wage Rate**	**Respondent Cost**
RPPR (or 2590 or 416-9)	40,569	1	15	$35.00	$21,298,725
PHS 416-7	3,371	1	30/60	$35.00	$58,993
PHS 2271	15,500	1	15/60	$35.00	$135,625
PHS 6031-1	1,600	1	20/60	$35.00	$18,480
HHS 568	22,681	1	5/60	$35.00	$63,507
Final Progress Report	22,681	1	1	$35.00	$793,835
iEdison	6,000	1	15/60	$35.00	$52,500
PHS 3734	584	1	6/60	$35.00	$2,044
TOTALS	**112,986**		**5.6**		**$22,423,709**

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 receiving PHS funding.

14. Annualized Cost to the Federal Government

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

15. Explanation for Program Changes or Adjustments

This submission represents program changes; previous estimated total burden hours for 0925-0002 was 132,501, current estimated total burden hours for 0925-0002 is 640,677. The increase of 508,176 is attributed to the reconfiguration of 0925-0001 and 0925-0002 into pre- and post-award forms as detailed in Attachment 1. Specific program changes for items now under 0925-0002 are described below:

a. Accuracy of Burden Hours Based on Number of Respondents. As NIH systems and grantee submissions become more automated NIH is able to provide increasingly accurate estimates of the number of forms completed each year based on a previous year model. The numbers provided under item 12 above are based on actual submissions of forms in FY11 and differ slightly from previous PRA estimates.

b. Implementation of the RPPR. The PHS implementation utilizes the standard cover page data elements and reporting categories of the RPPR Final Format, although not all components of Optional Categories are adopted. The SF 424(R&R) budget forms (cleared under OMB 4040-0001 and provided as part of the RPPR Final Format) will be adopted only for awards that require a budget as part of the progress report (less than 20% of awards). Where necessary, program-specific instructions are incorporated to clarify agency requirements and distinguished from standard RPPR instructions by the HHS logo. Some components of Optional Categories are adopted only for specific types of awards to accommodate the diversity of PHS awards (e.g., question about technology transfer will be implemented for SBIR/STTR awardees only). Agency or program-specific adjustments to the RPPR are minimized to the extent possible

and delineated in the table below. All agency or program-specific requirements are currently cleared under the PHS 2590 or 416-9 with the exception of D.1 and G.9. Information related to ClinicalTrials.gov reporting (G.4) is reduced from the 5 elements currently required in the PHS 2590 instructions at 2.2.6.D, to one element in the RPPR. With the implementation of the RPPR NIH will no longer require dates of Institutional Review Board or Institutional Animal Care and Use Committee approval in a progress report, but will rely on the institutional assurance of compliance with respective regulations and policy.

Agency or Program-Specific Reporting Requirements	
RPPR Reporting Category	**Justification**
A. Cover Page	
B. Accomplishments	
3. Competitive Revisions/Administrative Supplements	Need for specific location for grantees to report accomplishments of supplemental awards received under the parent award
C. Products	
1. Publications	The eRA Commons utilizes an electronic interface with the National Library of Medicine (in accord with legislative mandates included in the NIH Public Access Policy. GPS 8.2.2) that precludes use of the Data Dictionary publications elements. All publications are prepopulated from the Program Director/Principal Investigator's My NCBI account.
4. Inventions, patent applications and/or licenses	Grantees report detailed data through the interagency iEdison system; use of Data Dictionary elements would be redundant.
5.b. Resource sharing	NIH policy requires that research resources (e.g., data, model organisms) developed as a result of funded research be made available to the public that such availability be described in the progress reprot (GPS, 8.2.3).
D. Participants	
1. - Last 4 digits of SSN and MO/YEAR of birth - Name of organization if participant's primary affiliation is with a foreign organization	- See item 11 above. - Name of organization is required to assist with identification of foreign components (see G.9) below.
2. Personnel Updates	Information about participant involvement that is necessary for agency monitoring of awards: level of effort, new senior/key personnel, changes in other support, new other significant contributors, and changes to a multiple PI leadership plan.

Agency or Program-Specific Reporting Requirements	
RPPR Reporting Category	**Justification**
E. Impact	
E.3.a. and b. Status of commercialization activities and FDA approval	Applicable only to SBIR/STTR grantees (Congressionally-mandated set-aside programs for domestic small business concerns to engage in Research/Research and Development that has the potential for commercialization).
F. Changes	
3.d. Significant changes to use of select agents	Necessary to monitor grantee use of select agents per the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.
G. Special Reporting Requirements	
2. Responsible Conduct of Research	Applicable to Career Development, Fellowship and Education awards per NIH policy on research integrity.
3. Mentor's Report/Sponsor Comments	Applicable to Career Development (mentor's report) and Fellowship awards (sponsor comments), and necessary to evaluate supportee's progress and performance.
4. Human Subjects	Necessary to monitor projects that involve human subjects as required by regulation and policies (45CFR46.120, clinical trials and inclusion enrollment reporting, and ClinicalTrials.gov registration).
5. Human Subjects Education Requirement	Necessary to monitor compliance with NIH policy on required education in the protection of human subjects.
6. Human Embryonic Stem Cells (hESCs)	Necessary to monitor grantee use of hESCs under Federal Policy and the NIH Guidelines on Human Stem Cell Research.
7. Vertebrate Animals	Necessary to implement requirements of the PHS Policy on Humane Care and Use of Laboratory Animals.
8. Project/Performance Sites	Necessary to appropriately monitor all performance sites.
9. Foreign Component	Necessary to help meet the goals of the Administration's open government directive and Global Health Initiative by allowing NIH to more effectively track and report on its international collaborations in health-related research.
G.10 Estimated Unobligated Balance	Applicable to certain awards to appropriately monitor spending and use of carryover.
G. 11 Program Income	Applicable to certain awards to ensure subsequent funding is offset by any earned program income as applicable.

Agency or Program-Specific Reporting Requirements	
RPPR Reporting Category	**Justification**
G. 12 F&A Costs	Applicable to certain awards to appropriately determine funding level for subsequent year.
H. Budget	
PHS 398 Training Budget and Subaward Budget Attachment Form (cleared under OMB 0925-0001)	Applicable to training awards.

c. **Less data necessary on PHS 3734.** The Relinquishing Statement will no longer require the estimated date of the PI's departure or the signature of a Financial Officer.

d. **Final Progress Report Instructions.** Final Progress Report instructions, previously approved as part of the PHS 2590 (former Section 3 for non-SBIR/STTR awardees and Section 7 for SBIR/STTR Phase II awardees) are provided separately (Attachment 13) in anticipation of the RPPR replacement of the PHS 2590. In addition, the SBIR/STTR Phase II Final Progress Report instructions include a new format that clarifies the information requested to facilitate NIH reporting to Congress and the Small Business Administration (SBA) on the commercialization activities of NIH SBIR/STRR awards. NIH will also use this information to increase effective management of the SBIR/STTR program by evaluating the commercial, research and development, and regulatory status of outcomes and impacts on small businesses as a result of SBIR/STTR awards. There are two changes to the information required of SBIR/STTR Phase II awardees: (a) the All Personnel Report is no longer requested as part of the final report, and (b) the CMS reimbursement approval status of the product, process, or service, is requested. The latter is important because, along with an appropriate regulatory path, it is an essential component of commercializing a biomedical product. Without an effective reimbursement strategy companies cannot attract outsides investment or remain financially viable. NIH is committed to developing programs that maximize the success of SBIR/STTR awardees in achieving the goal of commercializing their technology to protect or improve human health. Understanding awardees' reimbursement strategy and success rates will better enable NIH to evaluate existing programs and design new programs in the future.

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

Supporting Statement Attachments

Attachment 1 - Table of Former and Revised Content of Information Collections
Attachment 2 – CFDA
Attachment 3- PHS 2590 forms
Attachment 4 – PHS 2590 instructions
Attachment 5 – PHS 416-9 forms
Attachment 6 – PHS 416-9 instructions
Attachment 7 – RPPR Screen Shots
Attachment 8 – RPPR Instructions for Grantees
Attachment 9 – PHS 416-7 form and instructions
Attachment 10 – PHS 2271 form and instructions
Attachment 11 – PHS 6031-1 form and instructions
Attachment 12 – HHS 568 form and instructions
Attachment 13 – Final Progress Report Instructions
Attachment 14 – PHS 3734 form and instructions