Supporting Statement A

PHS Research Performance Progress Report and Other Post-award Reporting [OD/OPERA] 0925-0002

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Check off which applies:

Revision

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A. Justification

The National Institutes of Health (NIH) and other Public Health Service (PHS) 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 0925-0002 revision submission represents a collection of post-award reporting requirements previously collected under 0925-0002. Pre-award reporting requirements are simultaneously consolidated under 0925–0001 (expiration March 31, 2020) and the changes to the collection here are related. These updates fully implement the final and interim RPPR, and make updates to align with system enhancements and changes to key policies, including the requirement to submit SBIR/STTR Life Cycle Certification forms.

A.1. Circumstances Making the Collection of Information Necessary

Several PHS Agencies in addition to the NIH utilize the Research Performance Progress Report (RPPR) and other forms under 0925-0002, including the Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA). Ruth L. Kirschstein National Research Service Awards (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 (HRSA)). The Indian Health Service (IHS) utilizes the PHS 2590 for one program. Participating agencies in the Small Business Innovation Research and Small Business Technology Transfer (SBIR/STTR) grant programs include the Administration for Children and Families (ACF), CDC, and FDA. The Administration for Community Living (ACL) may participate in the near future as well.

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 was 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. This information collection is currently approved under OMB 0925-0002, expiration October 31, 2018. Awards are issued under various NIH programs, which 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. These reports are submitted via the RPPR module (see attachment 5 for RPPR screen shots and Attachment 6 for RPPR instructions).

The PHS 2590 Non-Competing Continuation Progress Report (see Attachment 3 for forms and Attachment 4 for instructions) is restricted to progress reports for administrative extensions (Type 4s; e.g., SBIR/STTR Fast-Track Phase II application), and also used for multi-year funded awards within AHRQ.

Final RPPR: In order to continue the transition to a standard reporting format for all federally-funded research projects and research-related activities, PHS agencies will utilize the Final RPPR for closeout. Generally, the Final RPPR format will be the same as the current interim/annual RPPR, making it easier for grantees to navigate and complete (see attachment 21 for Final RPPR screen shots). Effective January 2017 (June 30, 2017 for SBIR/STTR Phase II awards), the Final RPPR has replaced the Final

Progress Report. NIH no longer accepts the Final Progress Report. The RPPR instructions have been updated to include Final RPPR guidance.

Other post-award information collections are necessary as follows:

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 12 for instructions and form).

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 13 for instructions and form).

PHS 6031-1: NRSA Annual Payback Activities Certification documents payback service and acceptance by PHS (see Attachment 14 for instructions and form). NRSA specific forms (PHS 416-7, 2271, and 6031-1) are utilized only by agencies with NRSA authority (NIH, AHRQ, and the Heath Research and Services Administration (HRSA)).

HHS 568: Final Invention and Certification Statement documents compliance with HHS invention/patent reporting requirements (see Attachment 15 for instructions and form)

iEdison: Necessitated by the Bayh-Dole Act invention and patent reporting requirements (35 USC 202 and 37 CFR 401) (see iEdison, and Attachment 16 for system screen shots).

Final Progress Report: Effective January 1, 2017 (June 30, 2017 for SBIR/STTR Phase II awards), NIH replaced the Final Progress report with the Final RPPR. NIH no longer accepts the Final Progress Report.

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 18 for instructions and form.)

SBIR/STTR Life Cycle Certifications: For new or continuing SBIR and STTR awards, a life cycle certification is required to be completed once certain milestones are reached during the project period. Effective January 1, 2019, NIH requires the submission of all SBIR/STTR Life Cycle Certification forms in each Interim and Final Research Performance Progress Report (I-RPPR and F-RPPR) submitted for SBIR/STTR grant awards. This update is also relevant for CDC and FDA SBIR awardees (see Attachment 20 for instructions and forms).

A.2. Purpose and Use of the Information Collection

Since the last OMB approval, NIH has worked on enhancing the reporting requirements on new policies through the RPPR, which are necessary to continue enhancing the quality of basic and preclinical research, as well as NIH-funded clinical trials. Some policy updates that are included in the 0925-0002 revision request include the following:

i. Implementation of the Final and Interim RPPR. Effective February 9, 2017, if the recipient organization has submitted a renewal application on or before the date by which a Final RPPR would be required for the current competitive segment, then submission of an "Interim-RPPR" via eRA Commons is now required. NIH has discontinued the policy for renewal applications whereby, “whether funded or not,” the progress report contained in the renewal application may serve in lieu of a separate final progress report.

ii. Removal of question G.4, and updates throughout to reference the Human Subjects System, which has replaced the Inclusion Management System, where inclusion and human subjects data is entered and updated.

iii. Upcoming edits to the budget form. In its updates to the pre-award reporting requirements, consolidated under 0925–0001, NIH has incorporated additional application requirements related to proposed human fetal tissue research due to Congressional ((Sections 498A and 498B of the PHS Act (42 U.S.C. 289g-1 and 289g-2)) and Department of Health and Human Services (45 C.F.R. 46.204 and 46.206) mandates. NIH has not implemented related changes to the RPPR at this time but anticipates that changes may be required in a subsequent submission.

iv. In Section D, added functionality to allow recipients to report effort for researchers working on the project to the nearest one-tenth, rather than in whole months as previously required.

v. SBIR/STTR grantees are now required to provide a copy of the SBIR/STTR Life Cycle Certification form in G.1: Special Notice of Award and Funding Opportunity Announcement Reporting Requirements

vi. Upcoming edits to the way NIH requests and captures Other Support information (e.g. Other Support format page). NIH has not implemented related changes to post-award reporting requirements at this time but anticipates that changes may be required in a subsequent submission.

RPPR,PHS 2590, and Final RPPR - Information collected as part of interim/annual and final 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. Within interim progress reports (either RPPR or PHS 2590), a grantee may submit a new biosketch if there are new senior/key personnel. For specific training grants, data on trainees and/or program statistics are required via a training data table and a completed trainee diversity report.

The RPPR is used for interim/annual 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. As of October 17, 2014, NIH requires grantees to submit all type 5 progress reports using the RPPR module in eRA Commons.

In order to continue the transition to a standard reporting format for all federally-funded research projects and research-related activities, PHS agencies utilize the Final RPPR for closeout. Effective

January 1, 2017 (June 30, 2017 for SBIR/STTR Phase II awards), NIH has replaced the Final Progress report with the Final RPPR. In addition, effective February 9, 2017, if the recipient organization has submitted a renewal application on or before the date by which a Final RPPR would be required for the current competitive segment, then submission of an "Interim-RPPR" via eRA Commons is now required. NIH has discontinued the policy for renewal applications whereby, “whether funded or not,” the progress report contained in the renewal application may serve in lieu of a separate final progress report.

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.

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.

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 - Effective January 1, 2017 (June 30, 2017 for SBIR/STTR Phase II awards), NIH replaced the Final Progress report with the Final RPPR. NIH no longer accepts the Final Progress Report. The Final RPPR fulfills the requirements of 45 CFR 75.381 and agency close-out procedures. Final RPPR 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.

A.3. Use of Information Technology and Burden Reduction

a. Use of the eRA Commons and Data Dictionary for Progress Reports - The format of the interim/annual RPPR (and also the Final/Interim 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, most paper progress reports to NIH, FDA, AHRQ and CDC have been eliminated.

The 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 Biotechnology 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.

Publications arising from an award are reported to the RPPR using My Bibliography. My Bibliography is a reference tool that helps grantees create and save publication citations. These citations are then uploaded into an RPPR annually.

As necessary, award programs will continue to utilize the PHS 2590 until the transition to RPPR is completed, however, the majority of NIH awards are issued under the Streamlined Noncompeting Award Process (SNAP) and non-SNAP are required to submit progress reports electronically. These same awards, plus the cohort of awards that are NRSA Fellowships, are included in the latest phase of RPPR implementation, which took place in October 2014. Thus, over 95% of awards are using the RPPR.

b. 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 mandatory for NIH institutional training awards, and its use will continue expanding to other NIH research education and institutional career development awards.

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

e. HHS 568 and iEdison - NIH is coordinating a cross-agency initiative in accord with interagency work, 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 to the NIH Closeout Center via the eRA Commons.

g. Relinquishing Statement PHS 3734 - The PHS 3734 Relinquishing Statement may be submitted in paper or electronically via the eRA Commons.

h. Prior Approval - the current submission process for prior approval requests is through email or paper submission. NIH has developed an electronic submission option through the eRA Commons for applicants and grantees to submit these requests directly to the appropriate official. Review and approval will happen within this system, which is currently optional for applicants and grantees. Examples of prior approval requests include, but are not limited to: additional no-cost extension, extension greater than 12 months, or late notification of initial no-cost extension; change in Program Director/Principal Investigator. See Attachment 21 for screen shots of this new system.

i. Privacy Impact Assessment (PIA) - NIH grant systems, such as eRA and IMPAC II) are covered by a PIA. See Attachment 22 for the latest copy of the PIA.

A.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.

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

The procedures for small businesses and other small entities are the same as for other grantees. Interim progress reporting of SBIR/STTR awards occurs via the RPPR. Effective June 30, 2017 NIH implemented the Final RPPR for SBIR/STTR awards.

A.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 120 days of the end of a project (for project period end dates after October 1, 2014). It is not possible to collect this information less frequently.

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

There are no special circumstances for the collection of information requirements.

A.8.1 Comments in Response to the Federal Register Notice

An announcement was placed in the Federal Register, Vol.84 No.71, pages 14958-14959, on April 12, 2019 for public comment on the data collection project, thereby providing the grantee community an active voice in the revision process. One public comment was received.

A.8.2 Efforts to Consult Outside Agency

Other consultations occur regularly at NIH Regional Seminars on Program Funding and Grants Administration twice each year. Participation in the Federal Demonstration Project (FDP) ((http://thefdp.org), 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 post-award activities and reporting requirements. All questions, comments and discussions from these meetings and

throughout the year are duly noted and considered when modifying grant related information collections.

A.9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents.

A.10. Assurance of Confidentiality Provided to Respondents

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

A.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 adding the collection of the month/year of birth on the Report to assist with identifying individuals.

NIH no longer collects this information electronically within Section D. Participants on the RPPR. The PHS 2590, which is only used in rare circumstances when an electronic application is not able to be used, retains the optional columns for the last four digits of the SSN and DOB, NIH is not requesting this information and anticipates removing these elements in a future submission.

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).

A.12.1 Estimated Annualized Burden Hours

Burden on applicants and grantees is associated with the forms and all proposed changes in the forms; there is no burden associated with regulatory language. The estimated average time to complete the RPPR or PHS 2590 has increased to 18 hours. Included in this RPPR burden estimate are estimated times to complete specific parts of the report for certain grantees: a biosketch is required to be submitted if there are new senior/key personnel to report (which applies to fellowship and non-fellowship awards); one data table may be completed for certain Institutional Research Training awards; a Trainee Diversity Report is necessary for certain Training awards. This burden increase is due to the development of a new PHS Human Subjects and Clinical Trial Information form and subsequent Human Subjects Management System for reporting human subject, inclusion enrollment, and clinical trial data post-award. Both biosketch format pages (general and Fellowship) and the NRSA data tables (current set and new set) are included in both 0925-0001 and 0925-0002 collections.

The estimated average time to complete the Final RPPR is also 18 hours. While this is an increase in the estimated average time to complete the Final Progress Report (1 hour), the Final RPPR comes from a

federal government-wide transition to a standard reporting format for all federally-funded research projects and research-related activities.

Publication Reporting occurs if an award generates publications during the project year, the publications citations must be reported. Publication reporting takes 5 minutes on average, using this My Bibliography. My Bibliography automates much of the tracking, formatting and reporting tasks associated with section C1 the RPPR and the publication progress report section of the PHS2590. Respondents process an average of 3 publications annually.

The estimated average time to complete the 416-7 form remains at 30 minutes; the 2271 form remains at 15 minutes; and the 6031-1 form 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 time to complete the 3734 form remains at 30 minutes.

A.12-1 Estimated Annualized Burden Hours

Information Collection Forms	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
REPORTING				
PHS 416-7	12,580	1	30/60	6,290
PHS 6031-1	1,778	1	20/60	593
PHS 568	11,180	1	5/60	932
iEdison	5,697	1	15/60	1,424
PHS 2271	22,035	1	15/60	5,509
PHS 2590	243	1	18	4,374
RPPR – Core Data	32,098	1	8	256,784
Biosketch (Part of RPPR)	2,544	1	2	5,088

Data Tables (Part of RPPR)	758	1	4	3,032
Trainee Diversity Report (Part of RPPR)	480	1	15/60	120
PHS Human Subjects and Clinical Trial Information (Part of RPPR, includes inclusion enrollment report)	6,420	1	4	25,680
Publication Reporting	97,023	3	5/60	24,256*
Final RPPR – Core Data	18,000	1	10	180,000
Data Tables (Part of Final RPPR)	758	1	4	3,032
Trainee Diversity Report (Part of Final RPPR)	480	1	15/60	120
PHS Human Subjects and Clinical Trial Information (Part of Final RPPR, includes inclusion/enrollment)	3,600	1	4	14,400
PHS 3734	479	1	30/60	240
SBIR/STTR Phase II Final Progress Report	1,330	1	1	1,330
SBIR/STTR Life Cycle Certification	1,500	1	15/60	375
Total		**413,029**		**533,579**

*The frequency of responses was being calculated by 1 instead of 3.

A.12.2 Annualized Cost to Respondents

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

research institutions in both the private and public sectors, teaching and non-teaching setting etc. Since the respondent base is so wide, it is difficult to determine an accurate average hourly rates. Therefore the hourly rate used in this table is based on historical NIH figures NIH has captured over decades of administering this data collection.

A.12-2 Annualized Cost to the Respondents

Information Collection Forms	Total Burden Hours	Hourly Wage Rage	Total Respondent Cost
REPORTING			
PHS 416-7	6,290	$35.00	$220,150
PHS 6031-1	593	$35.00	$20,755
PHS 568	932	$35.00	$32,620
iEdison	1,424	$35.00	$49,840
PHS 2271	5,509	$35.00	$192,815
PHS 2590	4,374	$35.00	$53,090
RPPR – core data	256,784	$35.00	$8,987,440
Biosketch (Part of RPPR)	5,088	$35.00	$178,080
Data Tables (Part of RPPR)	3,032	$35.00	$106,120
Trainee Diversity Report (Part of RPPR	120	$35.00	$4,200
PHS Human Subjects and Clinical Trial Information (Part of RPPR, includes inclusion enrollment report)	25,680	$35.00	$898,800
Publication Reporting	24,256	$35.00	$848,960
Final RPPR – core data	144,000	$35.00	$5,040,000
Data Tables (Part of Final RPPR)	3,032	$35.00	$106,120

Trainee Diversity Report (Part of Final RPPR)	120	$35.00	$4,200
PHS Human Subjects and Clinical Trial Information (Part of Final RPPR, includes inclusion/enrollment)	$14,400	$35.00	$504,000
PHS 3734	240	$35.00	$8,400
SBIR/STTR Phase II Final Progress Report	1,330	$35.00	$46,550
Total Reporting Cost Burden			$15,649,955
SBIR/STTR Life Cycle Certification	375	$35.00	$13,125
Grand Total			$16,229,97065

A.13. Estimates of Other Total Annual Cost to Respondents or Record keepers

Other annual costs to respondents or record keepers are associated with customary and usual business or practices of organizations receiving PHS funding. There are no additional costs to the respondents associated with the data collections within this ICR.

A.14. Annualized Cost to the Federal Government

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

Annualized Cost to the Federal Government

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

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

A.15. Explanation for Program Changes or Adjustments

In the burden table the frequency for Publication Reporting was being calculated as 1 instead of 3 in previous submissions, as well as in the current submission. A decrease of 2,000 burden hours is due to the Final Progress Report no longer being accepted. Overall, the burden hour estimates for other PHS forms did not change.

A Summary Table of Noteworthy Changes or Adjustments:

Form	**Adjustments**
Attachment 10A-D: Attachment Data tables for use with Institutional Research Training grant applications using the SF424 (R&R)	Updated language re: human subjects, inclusion/enrollment/study populations, clinical trials.
PHS 2271: Statement of Appointment	Section D: Updates to allow reporting of participant effort rounded to the nearest one-tenth, rather than whole numbers. Updates made to Section G: Special Reporting Requirements re: collection of human subject, inclusion, and clinical trial results/data/information in the Human Subjects System Removal of question G.4,

	Addition of requirement for SBIR/STTR recipients to upload the LifeCycle Certification form in G.1
Attachment 5B: PHS Human Subjects and Clinical Trial Information (Part of RPPR, includes Inclusion Enrollment Report)	Updated instructions and samples.
	Added two data fields. Updated instructions.
	Updates made to the PHS Human Subjects and Clinical Trial Information form. Reorganized and updated main PHS Human Subjects and Clinical Trial Information form introduction for clarity and streamlined instructions. Sections were renumbered accordingly. Added attachments to the PHS Human Subjects and Clinical Trials Information Study Record subform and Inclusion Enrollment Report subform. Added attachment 2.3.a. to the Study Record subform. Deleted field 4.1. Renumbered other sections accordingly. Updated field 4.1.a for clarity. Added field 4.6. Renumbered other sections accordingly. Added field 1 to the Inclusion Enrollment Report subform. Renumbered other sections accordingly. Removed previously numbered 5.1, 5.2, 5.6, 5.8, 5.11, 5.14, and 5.18 and renumbered section accordingly.

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

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

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

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

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

This project conforms to all of the 5 CFR 1320.9 requirements; no exceptions are requested.