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

This collection under 0925-0002 expiration date 2/2023 is being revised to convert the Inclusion Enrollment Report form to a Common form to include the Department of Defense (DoD) and any other agencies who wishes to use this form in the future. The forms original use will remain the same from previous submissions however, it will take on a new OMB# and expiration date from the other forms associated with this submission. The Inclusion Enrollment Report is used for all applications involving NIH-defined clinical research. This form is used to report both planned and cumulative (or actual) enrollment, and describes the sex/gender, race, and ethnicity of the study participants. In addition to converting the Inclusion Enrollment Report to a common form, other revisions include NIH requiring applicants and recipients to provide their Unique Entity Identifier (UEI) instead of the Data Universal Number System (DUNS) number starting in January 2022. Also, the application forms will be updated to align with the Grants.gov updated Country and State lists.

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. 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). SBIR/STTR Phase II awards, the Final RPPR 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). In a few years this system will be transferred to the National Institute of Standards and Technology (NIST) and will no longer be an NIH system.

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. NIH will continue to require 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 this revision request which includes the following:

i. Starting in January 2022, NIH will require will applicants and recipients to provide their Unique Entity Identifier (UEI) instead of the Data Universal Number System (DUNS) number. This change is in accordance with the Federal-wide transition from the DUN and Bradstreet (D&B) DUNS number to a new Government-owned Unique Entity Identifier mandated to be complete by April 2022. All application forms and instruments requesting an applicant entity's DUNS will be changed to request their UEI. All NIH electronic systems will also be enhanced to collect the UEI; DUNS will be maintained for historical informational purposes.

ii. The NIH continues to support international cooperation and scientific progress as a leader in global health. All NIH application forms and systems will be enhanced to reflect the recently updated Country and State lists in accordance with the updates from Grants.gov. This list of countries is based on the Geopolitical Entities, Names, and Codes (GENC) Standard Edition 3.0 Update 11.

iii. The NIH has implemented the updated Biographical Sketch format page and Other Support format page as captured in the last change request, and the new format pages will be required starting in January 2022. NIH is also moving towards implementation of convenient templates in SciENcv and anticipates future enhancements to better facilitate electronic submission for applicants.

iv. As part of ongoing efforts to support family-friendly work environments for the NIH-supported workforce, in April 2021 the NIH began providing support for childcare costs to recipients of Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellowships. Eligible recipients may now submit a request for these costs as part of the RPPR. NIH will also be expanding eligibility to full-time predoctoral and postdoctoral trainees appointed on NRSA institutional training awards within Fiscal Year 2022. 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.

v. The NIH will now require that the trainee diversity report be submitted electronically for recipients receiving institutional research training, career development and research education awards to submit the Trainee Diversity Report required with Research Performance Progress Reports (RPPRs), Interim Final RPPRs, and Final RPPRs electronically, using a new option that will be provided in the xTrain and RPPR modules. This requirement is only for those awards that require appointments through the xTrain system and will leverage existing electronic demographic data entered by the trainees in their eRA Commons Personal Profile to minimize the need for manual data entry by recipients thereby reducing administrative burden.

vi. The NIH will add a new element to the Cover Page of the RPPR to allow recipients to designate the Authorized Organizational Representative to be identified on the HHS mandated standardized Notice of Award Page One for all HHS awarding agencies.

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. 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. In June 2017 for SBIR/STTR Phase II awards, NIH has replaced the Final Progress report with the Final RPPR. In addition, effective February 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 – For the 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 back in October 2014. Thus, over 95% of awards are using the RPPR. The PHS 2590 Non-Competing Continuation Progress Report is restricted to progress reports for administrative extensions (Type 4s; e.g., SBIR/STTR Fast-Track Phase II application),

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. xTrain is also used for the electronic submission of the trainee diversity report as part of the RPPR; this is mandatory for institutional research training, career development and research education awards that require appointments through the xTrain system. This new electronically generated report

will leverage existing electronic demographic data entered by trainees in the Personal Profile of eRA Commons to minimize the need for manual data entry by recipients.

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. Since June 30, 2017, NIH continues the use of 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. 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, pages 18994-18995 (86 FR 18994) , on April 12, 2021 for public comment on the data collection project, thereby providing the grantee community an active voice in the revision process. No public comments were received.

A.8.2 Efforts to Consult Outside Agency

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.

NIH no longer collects this information electronically within Section D. Participants on the RPPR and the elements have also been removed from the PHS2590 as part of this 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

Information Collection Forms	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annua Burden Hou
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
Recording Burden Total				531,874
RecordKeeping				
SBIR/STTR Life Cycle Certification	1,500	1	15/60	375

Total	**217,653**	**411,699**		**532,249**

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.

A.12-1 Estimated Annualized Burden Hours

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 rate. 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
Total Reporting Cost Burden			$15,649,955
SBIR/STTR Life Cycle Certification	375	$35.00	$13,125
Grand Total			$16,229,97065

(https://www.bls.gov/news.release/empsit.t19.htm)

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 $238,382. 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 Analyst	14/4	134,782	50%		67,391
NIH Health Scientist Administrator	15/4	158,541	50%		79,271
Contractor Cost					
2 field contractor staff (Ripple Effects Communications, Inc., Highrise Consulting, Inc.)		$91,720	50%		91,720
Travel					
Other Cost					
Total					238,382

https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2021/DCB.pdf

A.15. Explanation for Program Changes or Adjustments

Changes made reflect an adjustment in burden hours. A decrease of 1,330 burden hours is due to the SBIR/STTR 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 3-4: PHS 2590 (Paper)	Changed field DUNS to UEI. Removed SSN (Last 4) and DOB from All Personnel Report. Updated and clarified instructions.
Attachment 5: RPPR/Final RPPR core data	Added UEI field. Added new data fields for Notice of Award Authorized Official. Updated instructions in G.4 regarding reporting requirements for clinical trials. Added instructions for eligible Fellowship recipients to attach request for childcare costs in G.1. Updated B.4 instructions for applicable recipients required to submit the new electronic trainee diversity report. Updated and clarified instructions.
Attachment 12: PHS 2271: Statement of Appointment	Updated Amendment type options for item 4. Type of Action. Updated and clarified instructions.
Attachment 5B: PHS Human Subjects and Clinical Trial Information (Part of RPPR, includes Inclusion Enrollment Report)	Relabeled Single IRB Plan attachment. Added label to Inclusion Enrollment Report sub-form to reflect new form number resulting from conversion to Common form. Updated Country and State codes lists. Updated and clarified instructions.
Attachments 8A-B: Biographical Sketch (Non-Fellowship)	Incorporated changes from last change request. Updated and clarified instructions.
Attachment 9A-C: Biographical Sketch (Fellowship)	Incorporated changes from last change request. Updated and clarified instructions.
Attachment 20A-B: SBIR/STTR Life Cycle Certification	Updated instructions.
Attachment Att D: NIH Other Support and In Kind	Updated format page title to “PHS Other Support”. Clarified “Major Goals” element is required.

Format Page and Instructions	Incorporated changes from last change request. Added clarifying instructions.
Attachment 14: PHS 6031-1	Updated and clarified instructions.

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.