

Supporting Statement A for

PHS Research Performance Progress Report and Other Post-award Reporting

0925-0002

Expiration Date 01/31/2026

Date: August 8, 2024

Check off which applies:

Revision

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Table of contents

A.	Justification	4
A.1	Circumstances Making the Collection of Information Necessary	5
A.2	Purpose and Use of the Information Collection	7
A.3	Use of Information Technology and Burden Reduction	11
A.4	Efforts to Identify Duplication and Use of Similar Information	14
A.5	Impact on Small Businesses or Other Small Entities	14
A.6	Consequences of Collecting the Information Less Frequently	14

A.7	Special Circumstances Relating to the Guidelines of 5 CFR 1320.5	15
A.8.1	Comments in Response to the Federal Register Notice	15
A.8.2	Efforts to Consult Outside Agency	15
A.9	Explanation of Any Payment of Gift to Respondents	15
A.10	Assurance of Confidentiality Provided to Respondents	15
A.11	Justification for Sensitive Questions	16
A.12.1	Estimates of Hour Burden Including Annualized Hourly Costs	16
A.12-2	Annual Cost to respondent	22
A.13	Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers	24
A.14	Annualized Cost to the Federal Government	24
A.15	Explanation for Program Changes or Adjustments	25
A.16	Plans for Tabulation and Publication and Project Time Schedule	26
A.17	Reason(s) Display of OMB Expiration Date is Inappropriate	27
A.18	Exceptions to Certification for Paperwork Reduction Act Submissions	27

ATTACHMENTS

Attachment 1 - Table of Former and Revised Content of Information Collections

Attachment 2 - Assistance Listing/CFDA List

Attachment 3 - PHS 2950: Non-Competing Continuation Progress Report Form

Attachment 4 - PHS 2950: Non-Competing Continuation Progress Report Instructions

Attachment 5 - Research Performance Progress Report (RPPR)/Final RPPR Screen Shots and component forms (PHS Human Subjects and Clinical Trial Information form and Data Management and Sharing Plan format page)

5A: eRA RPPR Sample Screenshots

5B: PHS Human Subjects and Clinical Trial Information (HSCT) Form (Landing Page, Inclusion Enrollment Form, and Study Record Sections 1-6)

5C: Data Management and Sharing Plan Format

Attachment 6 - RPPR/Final RPPR Instructions for Recipients

Attachment 7- Trainee Diversity Report

7A: Trainee Diversity Report

7B: Trainee Diversity Report eRA xTrain Sample Screenshots

Attachment 8 - General Biographical Sketch Format Page, Instructions (use also for Fellowship Sponsor/Co-Sponsors), and Samples

8A: General (Non-Fellowship) Biosketch Format Page (Replaced Attachment Att A2)

8B: General (Non-Fellowship) and Fellowship Biosketch Instructions (Replaced Attachment Att B)

8C: General (Non-Fellowship) Biosketch Sample

8D: NIH Biographical Sketch Supplement (new, to replace NIH Biosketch format effective May 2025)

Attachment 9 - Fellowship Applicant Biographical Sketch Format Page (use only for individual predoctoral and postdoctoral fellowships, dissertation research grants [R36], and Research Supplements to Promote Diversity in Health-Related Research [Admin Supplement]) and Samples

9A: Fellowship Biosketch Format Page (Replaced Attachment Att A1)

9B: Postdoc Biosketch Sample

9C: Predoc Biosketch Sample

Attachment 10 - Data tables for use with Institutional Research Training grant awards

10A: Introduction to the Data Tables

10B: Undergraduate Training Tables

10C: Consolidated Predoc and Postdoc Training Tables

10D: International Training Tables

Attachment 11 - Publication Reporting (My Bibliography Screen Shots)

Attachment 12 - PHS 2271: Statement of Appointment

Attachment 13 - PHS 416-7: Termination Notice for National Research Service Award

Attachment 14 - PHS 6031-1: Annual Payback Activities Certification for National Research Service Award

Attachment 15 - HHS 568: Final Invention Statement and Certification

(PREVIOUSLY REMOVED) Attachment 16 - Interagency Edison Reporting System (iEdison) Screen Shots

(PREVIOUSLY REMOVED) Attachment 17 - Final Progress Report Instructions

Attachment 18 - PHS 3734: Official Statement Relinquishing Interest and Rights in a PHS Research Grant

Attachment 19 - Post-Award eRA Commons Screen Shots: xTrain

Attachment 20 - Certifications for SBIR/STTR grantees to confirm continuing compliance with program requirements

20A: SBIR Life Cycle Certification

20B: STTR Life Cycle Certification

Attachment 21 - Post Award eRA Prior Approval Screen Shots

Attachment 22 - Privacy Impact Assessment

Attachment Att A - See Attachments 9A (formerly Att A1) and 8A (formerly Att A2)

Attachment Att B - See Attachment 8B

Attachment Att C - Other Support Format Page

Attachment Att D - Other Support and In-Kind Instructions

A. Justification

This collection under 0925-0002 expiration date 01/31/2026 is being revised to update the non-competing progress report collections for the implementation of the final NIH Policy for Data Management and Sharing (DMS Policy) to promote the management and sharing of scientific data generated from NIH-funded or conducted research and other updates to institutional training grant and fellowship applications. Starting in Fiscal Year 2025, NIH will require recipients to submit and address Data Management and Sharing (DMS) Plans within the Research Performance Progress Report (RPPR) in accordance with the DMS Policy. The progress report forms will be updated to align with this requirement. Effective January 2025, NIH will be updating institutional training grant applications; relevant to progress reports, the Training Data Tables will be updated to reduce burden and promote consistent information collection, including limiting the scope of information collection to data only relevant to the training stage(s) of the proposed program in Table 1 and removing instructions in Table 8 that are reported within the RPPR. Effective for May 2025, NIH will adopt the Common Forms for Biographical Sketch and Current and Pending (Other) Support as part of the directive from Guidance for Implementing National Security Presidential Memorandum (NSPM)-33. The Common Forms are part of a separate OMB collection, approved under 3145-0279 (Expiration Date 10/31/2026). Elements that will be collected within the Common Forms will be removed from NIH's current NIH Biosketch and Other Support formats. NIH will continue to collect information not captured on the Common Forms to adhere to the agency's implementation of the NIH Peer Review Regulations at 42 CFR Part 52 as part of the NIH Biosketch form, to be renamed the NIH Biographical Sketch Supplement, to reflect the supplemental information requested. The application and progress report forms and associated instructions will be updated to align with these new requirements.

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 Health 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)

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 recipients (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. Effective January 2023, NIH required applicants and recipients to submit and address Data Management and Sharing (DMS) Plans within the SF-424 R&R application and the Research Performance Progress Report (RPPR) in accordance with the final NIH Policy for Data Management and Sharing (DMS Policy) to promote the management and sharing of scientific data generated from NIH-funded or conducted research. This submission updates the previously approved collection to further align with this requirement, updating RPPR Section C.5 and related instructions to capture progress information on the approved DMS Plan, effective with RPPRs submitted in Fiscal Year 2025. These changes will provide a structured mechanism, rather than free-text narrative, to enhance recipient reporting on information that was required with the implementation of the 2023 NIH DMS Policy. NIH anticipates that changes may be required in a subsequent submission or change memo as part final systems implementation and updates.
- ii. Effective January 2025, NIH will implement changes to training grant applications, including updates to the Training Data Tables to reduce burden and promote consistent information collection. Changes include including limiting the scope of information collection to data only relevant to the training stage(s) of the proposed program in Table 1 and removing instructions in Table 8 that are reported within the RPPR. As eRA system implementation details of the data tables in xTRACT are being finalized, NIH anticipates that changes may be required in a subsequent submission or change memo. These changes, developed based on feedback from internal and external stakeholders, are aligned within the application and progress reporting tables and associated instructions.
- iii. Effective for May 2025, NIH will adopt the Common Forms for Biographical Sketch and Current and Pending (Other) Support as part of the directive from Guidance for Implementing National Security Presidential Memorandum (NSPM)-33. The Common Forms are part of a separate OMB collection, currently approved under 3145-0279 (Expiration Date 10/31/2026). As such, duplicative elements that will be collected within the Common Forms will be removed from NIH's current NIH Biosketch and Other Support formats. NIH will continue to collect additional information not captured on the

Common Forms to adhere to the agency's implementation of the NIH Peer Review Regulations at 42 CFR Part 52 as part of the NIH Biosketch form, which will be renamed the NIH Biographical Sketch Supplement to reflect the supplemental information requested. To facilitate the completion of the Common Forms and the NIH Biographical Sketch Supplement, NIH will require the use of the Science Experts Network Curriculum Vitae (SciENCv) to complete and certify the forms electronically. As additional tools (e.g., an Application Programming Interface (API) to reduce the manual burden of completing the forms) and implementation details are being finalized, NIH anticipates that changes may be required in a subsequent submission or change memo. The application and progress report forms and associated instructions will be updated to align with these new requirements.

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 recipient 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.

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 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. 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) and a subset of progress reporting for complex multi-year funded awards.

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 required to submit the HHS 568 electronically to the NIH Closeout Center via the eRA Commons. The iEdison system has transitioned to the National Institute of Standards and Technology (NIST) under the Department of Commerce (DOC). NIST will maintain OMB clearance for iEdison under 0693-0090.

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 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 the system, which is currently optional for applicants and recipients. 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 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 Businesses 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 the 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 the 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.89 No. 100 pages 45000-45001, on May 22, 2024 for public comment. One public comment was received.

A.8.2 Efforts to Consult Outside Agency

Other consultations occur regularly at NIH Virtual Grants Conferences typically held annually. 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 of 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).

Note: NIH is engaged with HHS on implementation plans for Statistical Policy Directive No. 15: Race and Ethnicity Data Standards. No changes will be implemented as part of this current collection. Implementation based on NIH agency action plan(s) will be completed by March 28, 2029, as required.

A.12.1 Estimates of Hour Burden Including Annualized Hourly Costs

This revision request includes an estimated increase of 50,098 burden hours to align with the changes being implemented to the RPPR and Final RPPR for the collection of progress report information on the approved DMS Plan provide a structured, rather than free text, mechanism to report on information that was already required with the implementation of the 2023 NIH DMS Policy. The changes to the Training Data Tables are streamlining and clarifying the field elements and instructions but are not inherently changing the overall information being collected. The information collection that will be retained when the NIH Biographical Sketch Supplement replaces the NIH Biosketch format are the narrative portions of that instrument that

account for the majority of the burden. The addition of the NIH Biographical Sketch Supplement does not increase the overall burden as it will replace the NIH Biosketch Format upon its implementation. In summary, the overall estimates to burden are not anticipated to change. The new estimated total annualized burden hours are 629,088 hours. NIH is engaging in on-going efforts to evaluate the assessment of burden estimates how to improve them.

Table 12-1 Estimated Annualized Burden Hours

Attachment Name/Number	Information Collection Forms	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
REPORTING					
<ul style="list-style-type: none"> Attachment 13: PHS 416-7 Form and Instructions Attachment 19: Post Award eRA xTrain Sample Screenshots 	PHS 416-7	12,580	1	30/60	6,290
<ul style="list-style-type: none"> Attachment 14: PHS 6031-1 Form and Instructions 	PHS 6031-1	1,778	1	20/60	593
<ul style="list-style-type: none"> Attachment 15: HHS 568 Form 	HHS 568	11,180	1	5/60	932
<ul style="list-style-type: none"> Attachment 12: PHS 2271 Form and Instructions Attachment 19: Post Award eRA xTrain Sample Screenshots 	PHS 2271	22,035	1	15/60	5,509
<ul style="list-style-type: none"> Attachment 3: PHS 	PHS 2590	243	1	18	4,374

<ul style="list-style-type: none"> 2590 Forms • Attachment 4: PHS 2590 Instructions • Attachment 5C: Data Management and Sharing Plan Format • Attachment 7A: Trainee Diversity Report • Attachment 8A: NIH General Non-Fellowship Biosketch Format • Attachment 8B: General and Fellowship Biosketch Format Instructions • Attachment 8D: NIH Biographical Sketch Supplement • Attachment 9A: NIH Fellowship Biosketch Format • Attachment 9B: NIH Fellowship Biosketch_Predoc Sample • Attachment 9C: NIH Fellowship Biosketch_Postdoc Sample • Attachment 10A: Introduction to the Data Tables • Attachment 10B: Undergraduate Training Tables • Attachment 10C: Consolidated Pre and Postdoc Training Tables • Attachment 10D: International Training Tables 					
<ul style="list-style-type: none"> • Attachment 5A: eRA RPPR Sample 	RPPR -	32,098	1	9	288,882

<ul style="list-style-type: none"> Screenshots Attachment 5B PHS HSCT Landing Page Attachment 5B PHS Inclusion Enrollment Report (Part of HSCT) Attachment 5B HSCT Section 1-6 Attachment 5C: Data Management and Sharing Plan Format 	Core Data				
<ul style="list-style-type: none"> Attachment 8A: NIH General Non-Fellowship Biosketch Format Attachment 8B: General and Fellowship Biosketch Format Instructions Attachment 8D: NIH Biographical Sketch Supplement Attachment 9A: NIH Fellowship Biosketch Format Attachment 9B: NIH Fellowship Biosketch_Predoc Sample Attachment 9C: NIH Fellowship Biosketch_Postdoc Sample 	Biosketch (Part of RPPR)	2,544	1	2	5,088
<ul style="list-style-type: none"> Attachment 10A: Introduction to the Data Tables Attachment 10B: Undergraduate Training Tables Attachment 10C: Consolidated Pre and Postdoc Training Tables Attachment 10D: International Training 	Data Tables (Part of RPPR)	758	1	4	3,032

Tables					
<ul style="list-style-type: none"> Attachment 7A: Trainee Diversity Report Attachment 7B: Trainee Diversity Report_xTrain Sample Screenshots 	Trainee Diversity Report (Part of RPPR)	480	1	15/60	120
<ul style="list-style-type: none"> Attachment 5B PHS HSCT Landing Page Attachment 5B PHS Inclusion Enrollment Report (Part of HSCT) Attachment 5B HSCT Section 1-6 	PHS Human Subjects and Clinical Trial Information (Part of RPPR, includes inclusion enrollment report)	6,420	1	4	25,680
<ul style="list-style-type: none"> Attachment 11: My Bibliography Sample Screenshots 	Publication Reporting	97,023	3	5/60	24,256
<ul style="list-style-type: none"> Attachment 5A: eRA RPPR Sample Screenshots Attachment 5B PHS HSCT Landing Page Attachment 5B PHS Inclusion Enrollment Report (Part of HSCT) Attachment 5B HSCT Section 1-6 Attachment 5C: Data Management and Sharing Plan Format 	Final RPPR - Core Data	18,000	1	11	198,000
<ul style="list-style-type: none"> Attachment 10A: Introduction to the Data Tables Attachment 10B: Undergraduate Training Tables Attachment 10C: Consolidated Pre and Postdoc Training Tables Attachment 10D: International Training 	Data Tables (Part of Final RPPR)	758	1	4	3,032

Tables					
<ul style="list-style-type: none"> Attachment 7A: Trainee Diversity Report Attachment 7B: Trainee Diversity Report_xTrain Sample Screenshots 	Trainee Diversity Report (Part of Final RPPR)	480	1	15/60	120
<ul style="list-style-type: none"> Attachment 5B PHS HSCT Landing Page Attachment 5B PHS Inclusion Enrollment Report (Part of HSCT) Attachment 5B HSCT Section 1-6 Attachment 5B_PHS HSCT Form Instructions_FORMS-I 	PHS Human Subjects and Clinical Trial Information (Part of Final RPPR, includes inclusion/enrollment)	3,600	1	4	14,400
Attachment 18: PHS 3734 Form	PHS 3734	479	1	30/60	240
Attachment 5C: Data Management and Sharing Plan Format	Data Management and Sharing Plan (Part of RPPR)	15,649	1	2	31,298
Attachment 5C: Data Management and Sharing Plan Format	Data Management and Sharing Plan (Part of Final RPPR)	8,621	1	2	17,242
Reporting Burden Total					629,088
Record Keeping					
<ul style="list-style-type: none"> Attachment 20A: SBIR Life Cycle Certification Attachment 20B: STTR Life Cycle Certification 	SBIR/STTR Life Cycle Certification	1,500	1	15/60	375
Total		236,226	430,272		629,463

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.12-2 Annual Cost to respondent

The hourly rate used for all burden hours (\$52.36) is based on the civilian education and health services occupational group reported by the U.S. Bureau of Labor Statistics from March 2024.

Table 12-2 Annualized Cost to Respondents

Information Collection Forms	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
REPORTING			
PHS 416-7	6,290	\$52.36	\$329,344.40
PHS 6031-1	593	\$52.36	\$31,049.48
PHS 568	932	\$52.36	\$48,799.52
PHS 2271	5,509	\$52.36	\$288,451.24
PHS 2590	4,374	\$52.36	\$229,022.64
RPPR – core data	288,882	\$52.36	\$15,125,861.52
Biosketch (Part of RPPR)	5,088	\$52.36	\$266,407.68
Data Tables (Part of RPPR)	3,032	\$52.36	\$158,755.52
Trainee Diversity Report (Part of RPPR)	120	\$52.36	\$6,283.20
PHS Human Subjects and Clinical Trial Information (Part of RPPR, includes inclusion enrollment report)	25,680	\$52.36	\$1,344,604.80
Publication Reporting	24,256	\$52.36	\$1,270,044.16
Final RPPR – core data	198,000	\$52.36	\$10,367,280.00
Data Tables (Part of Final RPPR)	3,032	\$52.36	\$158,755.52
Trainee Diversity Report (Part of Final RPPR)	120	\$52.36	\$6,283.20
PHS Human Subjects and Clinical Trial Information	14,400	\$52.36	\$753,984.00

(Part of Final RPPR, includes inclusion/enrollment)			
PHS 3734	240	\$52.36	\$12,566.40
Data Management and Sharing Plan (Part of RPPR)	31,298	\$52.36	\$1,638,763.28
Data Management and Sharing Plan (Part of Final RPPR)	17,242	\$52.36	\$902,791.12
Total Reporting Cost Burden			\$32,939,047.68
SBIR/STTR Life Cycle Certification	375	\$52.36	\$19,635.00
Grand Total			\$32,958,682.68

*Bureau of Labor Statistics: The rate was obtained from the civilian education and health services occupational group:
<https://www.bls.gov/news.release/ecec.t02.htm>

A.13 Estimate of Other Total Annual Cost Burden 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. The estimated costs to respondents above are calculated based on the inflation-adjusted civilian education and health services occupational group as reported by the U.S. Bureau of Labor Statistics from March 2024.

A.14 Annualized Cost to the Federal Government

The estimated annual cost to the NIH is approximately \$171,495. This information is calculated based on the NIH salary and percentage of effort devoted by an NIH Systems Policy Analyst and NIH Supervisory Grants Management Specialist to preparing this submission. 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	14/6	162,629	50%		81,315
NIH Supervisory Grants Management Specialist	15/4	180,359	50%		90,180
Contractor Cost					
Travel					
Other Cost					
Total					171,495

** the Salary in table above is cited from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2024/DCB.pdf>.

A.15 Explanation for Program Changes or Adjustments

This revision request includes an estimated increase of 50,098 burden hours to align with the changes being implemented to the RPPR and Final RPPR for the collection of progress report information on the approved DMS Plan provide a structured, rather than free text, mechanism to report on information that was already required with the implementation of the 2023 NIH DMS Policy. The changes to the Training Data Tables are streamlining and clarifying the field elements and instructions but are not inherently changing the overall information being collected. The information collection that will be retained when the NIH Biographical Sketch Supplement replaces the NIH Biosketch format are the narrative portions of that instrument that account for the majority of the burden. The addition of the NIH Biographical Sketch Supplement does not increase the overall burden as it will replace the NIH Biosketch Format upon its implementation. In summary, the overall estimates to burden are not anticipated to change. The new estimated total annualized burden hours are 629,088 hours. NIH is engaging in on-going efforts to evaluate the assessment of burden estimates how to improve them.

A Summary Table of Noteworthy Changes or Adjustments:

Form	Adjustments
Attachment 3-4: PHS 2590 Forms and Instructions	Updated and further streamlined form and instructions to align with previous clearances and minor copy editing.
Attachment 5 and 6: RPPR/Final RPPR core data and instructions	<p>Updated instructions for C.5. subsections for reporting progress on data management and sharing activities, if applicable.</p> <p>Updated instructions for SBIR/STTR RPPRs required to address any changes to the SBIR/STTR Foreign Disclosure Form (Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries [Exempt from Paperwork Reduction Act by SBIR and STTR Extension Act of 2022, P.L. 117-183]).</p> <p>Minor text updates.</p>
Attachment 8A_Att A2/8B_Att B/9A_Att A1: Biosketch (Non-fellowship) General and Fellowship Biosketch Instructions Biosketch (Fellowship)	Will no longer be used for due dates on or after May 25, 2025. Will be replaced by the Common Form for Biographical Sketch (OMB Number: 3145-0279 Expiration Date 10/31/2026) and the new NIH Biographical Sketch Supplement form (see Attachment 8D-E).
Attachment 8D: NIH Biographical Sketch Supplement and Instructions	New NIH Biographical Sketch Supplement form and instructions that will replace the current NIH Biosketch format page for both fellowship and non-fellowship applications effective for due dates on or after May 25, 2025 when NIH transitions to the Common Forms for Biographical Sketch and Current and Pending (Other) Support (OMB Number: 3145-0279 Expiration Date 10/31/2026). This new form will collect a subset of NIH-specific items currently on the NIH Biosketch format page.
Attachment 10A-D: Training Data Tables	<p>Updated table designations and formatting throughout data tables for consistent alignment with predoctoral, postdoctoral, undergraduate, etc.</p> <p>Removed duplicative information covered in the RPPR.</p> <p>Updated and clarified instructions.</p>
Attachment 19B: Post-Award eRA Commons Screen Shots_xTrain	Updated screenshots to reflect most recent xTrain system modernization.

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. Note: Forms developed by Grants.gov, under HHS, (i.e., Attachments 5B) display the OMB number and expiration date appropriately but the burden statement requires selecting a button to open the burden statement.

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.