U.S. Department of Health and Human Services
Public Health Service

Non-Competing Continuation Progress Report (PHS 2590)

Instructions for PHS 2590
Revised 01/2017

Forms Approved Through 08/31/2018
OMB No. 0925-0002

TABLE OF CONTENTS

Notable and Upcoming Changes

As detailed in Guide Notice NOT-OD-15-005, NIH has transitioned to a new module within the eRA Commons known as the Inclusion Management System (IMS) for reporting sex/gender, race, and ethnicity information as required by the NIH Policy on the Inclusion of Women and Minorities in Clinical Research. The previous system, known as the Population Tracking System, was retired in July 2014. NIH recipients submitting paper progress reports must now use the PHS Inclusion Enrollment Report format to report inclusion data.

As indicated in NIH Guide Notices NOT-OD-13-035, NOT-OD-14-026, and NOT-OD-14-092, the RPPR is now required for all NIH awards. In addition, as indicated in Guide Notice NOT-OD-17-022 the NIH replaced the Final Progress Report (FPR) with the Final Research Performance Progress Report (Final RPPR) through a new eRA Commons module effective January 2017. The NIH continues development of the Final RPPR for administrative extensions (Type 4s; e.g., SBIR/STTR Fast-Track Phase II applications) and will continue to update the community as progress is made.

All AHRQ recipients, exclusive of recipients of multi-year funded awards (awards in which the budget and project periods are the same and are longer than 12 months), will have the ability to use the eRA commons RPPR module beginning October 19, 2014. Effective January 1, 2015, AHRQ will require use of the RPPR module for all awards except multi-year funded awards. See Guide Notices NOT-HS-15-001 and NOT-HS-14-003.

In accordance with Guide Notice NOT-OD-12-160, NIH recipients submitting paper PHS 2590 progress reports (rare cases) are required to provide a My NCBI generated PDF list of publications as part of the progress report. The My NCBI PDF report will serve as Section 2.6.E., Publications.

For SBIR/STTR Fast-Track Phase II applications (SBIR/STTR Fast-Track Phase I final progress reports), follow the instructions in this document in Section 6.

Final Progress Report instructions are relocated to: http://grants.nih.gov/finalreport.pdf.

Please note the following mailing address change for NIH PHS 2590 progress reports:

Division of Receipt and Referral
Center for Scientific Review
National Institutes of Health
6701 Rockeledge Drive, Room 2040, MSC 7720
Bethesda, MD 20894-7720 (for regular or US Postal Service Express Mail)
Bethesda, MD 20817 (for other courier/express mail delivery only)

1. Continuation Progress Report

Progress reports are required to continue support of a PHS grant for each budget year within a competitive segment. The PHS 2590 may also be used for more frequent reporting requirements such as interim reporting. Instructions for submitting a Final Progress Report, required for any grant that is terminated, are found at http://grants.nih.gov/finalreport.pdf. For more information on the PHS 2590, contact Grants Information at GrantsInfo@nih.gov or call (301) 435-0714.

For all NIH awards (with the exception of non-competing Type 4s), the annual progress report must be submitted electronically through the eRA Commons electronic Research Performance Progress Report (RPPR) module. Do not use the PHS 2590 for any NIH annual progress report; any such report submitted on the PHS 2590 will not be accepted, and the recipient will be required instead to submit using the RPPR. Guidance on RPPR submission is documented in the NIH RPPR Instruction Guide found at: http://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf.

All AHRQ recipients, exclusive of recipients of multi-year funded awards (awards in which the budget and project periods are the same and are longer than 12 months), will have the ability to use the eRA commons RPPR module beginning October 19, 2014. Effective January 1, 2015, AHRQ will require use of the RPPR module for all awards except multi-year funded awards. See Guide Notices NOT-HS-15-001 and NOT-HS-14-003. Recipients of AHRQ multi-year funded awards should continue to use the PHS 2590 and any specific instructions in the Notice of Award.

CDC, FDA and IHS do not use the RPPR for progress reports at this time.

For SBIR/STTR Fast-Track Phase II applications (SBIR/STTR Fast-Track Phase I final progress reports), follow the instructions in this document in Section 6.

For NIH, the PHS 2590 will continue to be used only for non-competing Type 4 progress reports and/or more frequent reporting requirements as indicated in specific terms of award. These paper NIH progress reports must be submitted in hard copy to the centralized mailing address below, in accordance with the special instructions indicated in the Notice of Award:

Division of Receipt and Referral
Center for Scientific Review
National Institutes of Health
6701 Rockeledge Drive, Room 2040, MSC 7720
Bethesda, MD 20894-7720 (for regular or US Postal Service Express Mail)
Bethesda, MD 20817 (for other courier/express mail delivery only)
Phone Number: (301) 435-0715

Note that throughout these instructions are references to “competing application instructions.” “Competing application instructions” means either the SF424 (R&R) Application Guides (http://grants.nih.gov/grants/how-to-apply-application-guide.htm), or the PHS 398 Grant Application (http://grants.nih.gov/grants/funding/phs398/phs398.html).

1.1 Continuation Progress Reports for Other PHS Agencies

While other PHS awarding agencies use these same progress report forms, some may have application requirements that are different from those for NIH recipients. For agency specific instructions for AHRQ, CDC, FDA and IHS, refer to the terms and conditions of the Notice of Award (NoA) or their website listed in the table below.

References to the *NIH Grants Policy Statement (NIHGPS)* throughout these instructions apply only to NIH and not to the other PHS awarding agencies. The agencies listed below follow the Department of Health and Human Services Grants Policy Statement (HHSGPS) as their awarding guidance (http://www.hhs.gov/asfr/ogapa/grantinformation/hhsgps107.pdf).

OTHER PHS AWARDING AGENCIES	PHONE
AGENCY FOR HEALTHCARE RESEARCH AND QUALITY	301-427-1447
CENTERS FOR DISEASE CONTROL AND PREVENTION	1-800-232-4636
INDIAN HEALTH SERVICE	301-443-0578
FOOD AND DRUG ADMINISTRATION	301-827-7185

1.2 Submission of Progress Report for NIH Recipients

NIH recipients can determine which progress reports are due through the website located at: http://era.nih.gov/commons/quick_queries/index.cfm#progress. NIH recipients are responsible for periodically checking the list, which is updated on or around the 30th of each month. In addition to this website, automatic e-mail notifications are sent to the PD/PI.

Progress report due dates are also available in the eRA Commons Status system. For more information on the Commons, see: https://commons.era.nih.gov/commons/index.jsp.

For those few programs where a paper PHS 2590 is still used, NIH recipients submitting these reports are required to submit the completed, signed original PHS 2590 to the Division of Receipt and Referral. Copies are not necessary. **Do not bind or staple the original.** You may substitute computer-generated facsimiles for any of the forms. Substitute forms should be printed in black ink, and maintain the exact wording and format of the government-printed forms, including all captions and spacing. Any questions on completing this continuation progress report should be directed to the awarding component. The forms, in Adobe Acrobat and Microsoft Word, can be downloaded from the NIH web site at http://grants.nih.gov/grants/forms.htm.

Use English only and avoid jargon. If terms are not universally known, spell out the term the first time it is used and note the appropriate abbreviation in parentheses. The abbreviation may be used thereafter. Prepare the progress report single-sided and single-spaced. NIH requires the use of Arial, Helvetica, Palatino Linotype or Georgia typeface, a black font color and a font size of 11-points or larger. A symbol font may be used to insert Greek letters or special characters; the font size requirement still applies. These fonts will conform to appropriate formatting specifications. The progress reports must be clear and readily legible. Figures, charts, tables, figure legends, and footnotes may be smaller in size but must be black ink, readily legible, and follow the font typeface requirement.

An incomplete or incorrectly prepared continuation progress report may result in a delay in award of funds.

1.3 GrantsInfo, OER, National Institutes of Health

NIH Grants Information is a communications resource service for NIH grant-related inquiries. The e-mail address is: GrantsInfo@nih.gov. The phone number is (301) 435-0714, TTY (301) 451-5936.

The NIH grants Web site is at http://grants.nih.gov/grants/oer.htm.

1.4 Paperwork Burden

Public reporting burden for this collection of information is estimated to 15 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0002). Do not send progress reports to this address.

1.5 Registration Reminders

1.5.1 DUNS Registration for the Recipient Organization & Subaward/Consortium Organizations

A Data Universal Numbering System (DUNS) number is required for all progress reports-paper and electronic-and must be obtained prior to submission. For organizations that already have multiple DUNS numbers, one DUNS number should be selected by an AOR and used consistently for all submissions. The AOR should be consulted to determine the appropriate number to use.

The DUNS number is considered the Federally-recognized unique identifier and is used for reporting purposes, particular those associated with the *Federal Funding Accountability and Transparency Act (FFATA) of 2006* (P.L. 109-282).

FFATA also includes a requirement for reporting on subaward information. Therefore an accurate DUNS number for each first-tier subaward/consortium organization must also be provided as part of the Project/Performance Site Information.

Additional information on DUNS registration is found at:
http://fedgov.dnb.com/webform/displayHomePage.do.

A DUNS number is required for System for Award Management Registration (see 1.5.2 below).

1.5.2 System for Award Management (SAM) Registration for the Recipient Organization

Prior to submission of all progress reports-paper and electronic-organizations are required to be registered in the System for Award Management (SAM) (formerly CCR). Organizations must maintain the currency of the information in the registry and renew the registration annually or more frequently if required by changes in information or another award term. For additional information regarding maintaining an active SAM registration, see NIH Guide Notice NOT-OD-11-004.

SAM is a government-wide registry for organizations doing business with the U.S. Government. The registry collects, validates, stores, and disseminates data in support of agency acquisition missions,

including Federal agency contract and assistance awards. The SAM registry will be used by Federal agencies to validate the DUNS number provided. Validation of the DUNS number will be critical for agencies to comply with the requirements of the *Federal Funding Accountability and Transparency Act (FFATA) of 2006* (P.L. 109-282).

Organizational information entered into the SAM must match that in the eRA Commons. Since CCR Registration can take several days to complete, the process should be started well in advance of a submission date to avoid potential delays. An AOR should be consulted to determine if the organization has properly completed and maintained SAM registration. Use the SAM.gov "Manage Entity" function to manage entity registrations. See the Grants Registrations User Guide at http:///www.sam.gov for additional information.

2. General Instructions for Preparing Progress Reports

For submission of paper PHS 2590 progress reports, follow the instructions below, using the fillable PHS 2590 Forms posted at http://grants.nih.gov/grants/funding/2590/2590.htm.

2.1 Face Page

Items 1-5.

Provide the requested information, noting all changes in Section 12 of the Face Page.

Multiple PD/PIs: If multiple PD/PIs are part of the NIH approved project, use the Face Page-Continued page to provide items 2a – 2e for all PD/PIs. NIH requires one PD/PI be designated as the "contact PD/PI." This individual should be listed in block 2a of the Face Page with all additional PD/PIs listed on the Face Page - Continued.

If this progress report submission includes a change in the contact PD/PI, include the name and contact information for the new contact PD/PI in Section 2a of the Face Page (Form Page 1). Note this change in Section 12 of the Face Page. All other PD/PIs should be listed using the Face Page-continued page. Also address this change in the Progress Report Summary by indicating a Change in the Multiple PD/PI Leadership Plan. Remember, the designated contact PD/PI must be from the recipient institution if PD/PIs are from more than one Institution.

Item 6. Human Subjects

Policy on research involving human subjects can be found in the *NIH Grants Policy Statement* or the competing application instructions. Guidance pertaining to Human Subjects Research, including clinical trials and NIH-Defined Phase III Clinical Trials, may be found in Part II of the Supplemental Grant Instructions for All Competing Application and Progress Reports. Human subject definitions are found in Part III of the Supplemental Grant Instructions for All Competing Application and Progress Reports. Check "No" if activities involving human subjects are **not** planned **at any time** during the proposed budget period. The remaining parts of Item 6 are then not applicable.**Check "Yes"** if activities involving human subjects are planned **at any time** during the budget period, either at the applicant organization or at any other project/performance site or collaborating institution. "Yes" should be checked even if the research is exempt from HHS regulatory requirements for the protection of human subjects.

Appropriately designating whether human subjects are involved may facilitate processing of an award. Information about how the regulations apply to the proposed research may be obtained from the Office for Human Research Protections (OHRP), Department of Health and Human Services, http://www.hhs.gov/ohrp, or the program administrator in the awarding

component. The PHS will make a final determination as to whether the proposed activities are covered by the regulations (i.e., non-exempt) or are in an exempt category.

Exempt Research. If all the activities are designated to be exempt from the regulations, insert the exemption number(s) corresponding to one or more of the six exemption categories listed in the *NIH Grants Policy Statement* or the competing application instructions or the Protection of Human Subject regulations (45 CFR 46.101(b)). The remaining parts of Item 6 are then not applicable.

Non-Exempt Research. If any of the planned activities involving human subjects are not exempt, complete the remaining parts of Item 6. If the applicant organization has a current approved Federal Wide Assurance on file with the OHRP, insert the Assurance number and the most recent date of approval by the Institutional Review Board (IRB) for the proposed activities. This date must not be earlier than one year before the start date for which the Progress Report is submitted. **No Progress Report for continuation support should be submitted until the necessary certification of annual IRB review has been obtained.**

Item 7. Vertebrate Animals.

Policy on research activities involving vertebrate animals can be found in the *NIH Grants Policy Statement* or the competing application instructions. If activities involving vertebrate animals are **not** planned **at any time** during the proposed budget period, check "No." The remaining parts of Item 7 are then not applicable.

Check "Yes" if activities involving vertebrate animals are planned **at any time** during the budget period, either at the applicant organization or at any other project/performance site or collaborating institution. If the applicant organization has a current approved Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW), enter the Assurance number of the applicant organization in Item 7b. In addition, provide certification of current Institutional Animal Care and Use Committee (IACUC) approval of the animal activities. PHS Policy requires that IACUC approval occur within the past three years to be considered current. **Progress reports for continuation support should NOT be submitted until the necessary verification of IACUC review has been obtained**.

Item 8a. Direct Costs Requested for Next Budget Period

Enter the direct costs from Form Page 2.

Item 8b. Total Costs Requested for Next Budget Period

Enter the sum of the total direct costs from Item 8a and F&A costs.

Item 9. Inventions and Patents

Check "No," if no inventions were conceived or reduced to practice during the course of work under this project during the previous budget period.

Check "Yes," if any inventions were conceived or reduced to practice during the course of work under this project during the previous budget period. Check the appropriate box to indicate whether this information has or has not been previously reported to the PHS or to the official responsible for patent matters at the recipient organization.

According to NIH Grants Policy and Federal law, NIH recipient organizations must promptly report all inventions that are either conceived or first actually reduced to practice using NIH grant funds. Invention reporting compliance as specified at 37 CFR 401.14 is described at http://www.iedison.gov. The recipient is encouraged to submit reports electronically using Interagency Edison (http://www.iedison.gov). Inquiries or correspondence should be directed to:

Division of Extramural Inventions and Technology Resources

Office of Policy for Extramural Research Administration, OER, NIH
6705 Rockledge Dr., MSC 7980
Bethesda, MD 20892-7980
(301) 435-1986

Information from these reports is retained by the NIH as confidential and submission does not constitute any public disclosure. Failure to report as described at 37CFR Section 401.14 is a violation of 35 USC 202 and may result in loss of the rights of the recipient organization.

Item 10. Project/Performance Sites

Indicate where work described will be conducted. If work will be conducted at the applicant institution, state "applicant" under Name of Organization; it is not necessary to re-enter the address, DUNS, and Congressional District if it is the same as that provided in block 3 of the Face Page. If more than one site, use the Project/Performance Site Format Page to list all the sites, including Department of Veterans Affairs (VA) facilities and foreign sites. One of the sites indicated must be the applicant organization or be identified as off site in accordance with the applicant organization's negotiated Facilities and Administrative (F&A) agreement.

If including a NEW Project/Performance Site where either human subjects or vertebrate animals will be involved, indicate a change on the Progress Report Summary, Form Page 5, and address the change in the Summary under D. Plans, item A or B, as appropriate.

If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under an appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other NIH human subject related policies described in Part II of the Supplemental Grant Instructions for All Competing Application and Progress Reports and the *NIH Grants Policy Statement*.

For research involving live vertebrate animals, the applicant organization must ensure that all Project/Performance Sites hold OLAW-approved Assurances. If the applicant organization does not have an animal program or facilities and the animal work will be conducted at an institution with an Assurance, the applicant must obtain an Assurance from OLAW prior to an award.

Item 11. Official Signing for Applicant Organization

Name of individual authorized to act for the applicant organization and to assume the obligations imposed by the Federal laws, requirements, and conditions for a grant or grant application, including the applicable Federal regulations. Provide name, title and contact information for the signing official.

Item 12: Face Page Corrections and Changes

Use this space for corrections and changes.

Item 13. Applicant Organization Certification and Acceptance

An original signature, in ink, is required. Only an institutional official with formal designated or delegated authority to sign on behalf of the organization may sign the form. The signature must be dated. In signing the Face Page, the AOR of the applicant organization certifies that the applicant organization will comply with all applicable assurances and certifications listed below. The applicant organization is responsible for verifying the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in the progress report, including the Facilities and Administrative cost rate. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions, such as withdrawal of a progress report, suspension and/or termination of an award, debarment of individuals, as well as possible criminal penalties. The signer further certifies that the applicant organization will be accountable both for the appropriate use of

any funds awarded and for the performance of the grant-supported project or activities resulting from this progress report. The recipient institution may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.

Assurances/Certifications

Each progress report to the PHS requires that the following policies, assurances, and/or certifications be verified by the signature of the Authorized Organization Representative (AOR) on the Face Page of the progress report. The list of assurances, certifications, and other policies that apply to progress reports submitted to NIH and other PHS agencies is found in Part III of the Supplemental Grant Instructions for All Competing Application and Progress Reports. Applicants and recipients must comply with a number of additional public policy requirements. Contact the institution's research grant administrative office or refer to the *NIH Grants Policy Statement* for additional information.

The policies, assurances and certifications listed in Part III may or may not be applicable to certain projects, programs, or types of applicant organizations. If unable to certify compliance, provide an explanation and place it after the All Personnel Report Form Page 7 (4.1.7).

2.2 Detailed Budget for Next Budget Period (Not Applicable to SBIR/STTR Fast-Track Phase II Applications)

FORM PAGE 2

Itemize the direct costs requested for the next budget period by budget categories. Use the recommended direct cost shown on the spreadsheet included with the Notice of Award issued in the competitive year as the guide for developing the line item annual budget. Use Form Page 3 and continuation pages as necessary to provide required explanation of budget items.

For multi-project grants where individual projects are budgeted separately, additional copies of Form Page 2 should be prepared for each project or core in the program. Number these pages consecutively. Do not use suffixes such as 2a, 2b. On the individual budget pages for each specific project, clearly identify the name of the project leader and the title of the project.

Certain conditions may change the funding requirements for a budget period from those originally recommended. Such proposed funding changes, particularly increases over the recommended level, must be explained and fully justified for PHS awarding component consideration.

Name and Role on Project

Starting with the PD/PI(s), list all employees of the applicant organization who will be involved on the project for at least one person month or more, regardless of whether or not salaries are requested.

Months Devoted to Project. Enter the number of months devoted to the project. Three columns are provided depending on the type of appointment being reflected, academic, calendar, and/or summer months. Individuals may have consecutive appointments within a calendar year, for example for an academic period and a summer period. In this case, identify each appointment separately using the corresponding column.

If effort does not change throughout the year, use only the calendar months column. If effort varies between academic and summer months, leave the calendar months column blank and use only the academic and summer months columns. In cases where no contractual appointment exists with the applicant organization and salary is requested, enter the number of months devoted to the project period.

If a change in the level of effort for the PD/PI(s) or other Senior/Key Personnel designated on the NoA is proposed from what was approved in the competing year award of this project, a detailed justification must be provided under Section 2.3 Budget Justification.

Salary Requested

Regardless of the number of months being devoted to the project, enter the dollar amounts for each position for which funds are requested. The salary requested may not proportionally exceed any imposed salary limitation. Recipients are encouraged to check the NIH Guide for Grants and Contracts for the salary limitation each year (http://grants.nih.gov/grants/policy/salcap_summary.htm).

Fringe Benefits

Fringe benefits may be requested in accordance with the institutional guidelines for each position, provided the costs are treated consistently by the applicant organization as a direct cost to all sponsors.

Totals

Calculate the totals for each position and enter the subtotals in each column where indicated.

Special Instructions for Individuals with Joint University and Department of Veterans Affairs (V.A.) Appointments

Individuals with joint university and V.A. appointments may request the university's share of their salary in proportion to the effort devoted to the research project. The individual's salary with the university determines the base for computing that request. Signature by the institutional official on the application certifies that: (1) the individual is applying as part of a joint appointment specified by a formal Memorandum of Understanding between the university and the V.A.; and (2) there is no possibility of dual compensation for the same work, or of an actual or apparent conflict of interest regarding such work. Additional information may be requested by the awarding components.

Consultant Costs

Whether or not costs are involved, provide the names and organizational affiliations of all consultants, other than those involved in consortium/contractual arrangements. Include consultant physicians in connection with patient care and persons who serve on external monitoring boards or advisory committees to the project. Briefly describe on Form Page 3 any changes in services to be performed. Include the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs.

Equipment

List separately each item of equipment and justify the purchase on Form Page 3, if not previously approved.

Supplies

Itemize supplies in separate categories, such as glassware, chemicals, radioisotopes, etc. Categories in amounts less than $1,000 do not have to be itemized. If animals are to be purchased, state the species, strain(s), ages, sex, and the number of animals to be used.

Travel

Itemize travel requests and justify on Form Page 3. Provide the purpose and destination of each trip and the number of individuals for whom funds are requested.

Patient Care Costs

Indicate the basis for estimating costs in this category in detail, including the number of patient days, estimated cost per day, and cost per test or treatment. If both inpatient and outpatient costs are requested provide information for each separately, and if multiple sites are to be used, provide the information in detail for each site.

Include information regarding projected patient accrual for the budget period and relate this information to the budget request for patient care costs.

Provide specific information regarding anticipated sources of other support for patient care costs, e.g., third party recovery or pharmaceutical companies. Include potential or expected utilization of General Clinical Research Centers.

Patient care costs do **not** include travel, lodging, and subsistence or donor/volunteer fees. Request these costs in the Other Expenses category. Request the costs for consultant physician fees in the Consultant Costs category. Patient care costs will be provided to foreign organizations only in exceptional circumstances.

Alterations and Renovation

Itemize by category and justify on Form Page 3 the costs of essential alterations and renovations, including repairs, painting, removal or installation of partitions, shielding, or air conditioning. When applicable, indicate the square footage involved, giving the basis for the costs, such as an architect's or contractor's detailed estimate as outlined in the *NIH Grants Policy Statement*. Line drawings of the proposed alterations should be submitted with the progress report where required by the *NIH Grants Policy Statement*. Note, costs for any Alterations and Renovations (A&R) were previously unallowable from foreign institutions, international organizations and domestic applications with foreign subawards. However an HHS policy change now allows for minor A&R (<$500,000) on these applications. When requesting minor A&R costs under this policy, provide detailed information on the planned A&R in the budget justification.

Other Expenses

Itemize any other expenses by category and unit cost. These might include animal maintenance (unit care costs and number of days), patient travel, donor fees, publication costs, computer charges, rentals and leases, equipment maintenance, service contracts, and tuition remission when budgeted separately from salary/fringe benefits.

Consortium/Contractual Costs

Each participating consortium/contractual organization must submit a separate detailed budget (Form Page 2) and budget justification (Form Page 3) for the next budget period. If a new consortium is added, follow the guidelines in the competing application instructions.

List the Facilities and Administrative (F&A) costs, if any, and provide the basis for the rate in the Consortium/Contractual Costs category. Insert the page(s) for each consortium/contractual organization after Form Page 3 and number them consecutively.

The sum of all consortium/contractual costs (direct and F&A) must be entered in the Consortium/Contractual Costs category of the applicant organization's budget.

2.3 Budget Justification (Not Applicable to SBIR/STTR Fast-Track Phase II Applications)

FORM PAGE 3

Budget Justification

Provide detailed justification for those line items and amounts that represent a significant change from previously recommended levels (e.g., total rebudgeting greater than 25 percent of the total award amount for this budget period).

If there has been a significant change in the level of effort devoted to the project from what was approved in the competing year award for the PD/PI or other Senior/Key Personnel designated on the NoA, provide a justification of the reduction for those individuals. (A significant change in level of effort is defined in Federal regulations as a **25 percent reduction** in time devoted to the project.)

Current Budget Period

In the space provided, or on additional pages, explain any estimated unobligated balance of total costs (including prior year funds carried over) that is greater than 25 percent of the current year's total approved budget. Explain why there is a significant balance and how it will be spent if carried forward into the next budget period. The “total approved budget” equals the current fiscal year award authorization plus any carryover of funds from a prior year. The numerator equals the total amount available for carryover and the denominator equals the current year’s total approved budget.

2.4 Biographical Sketch

BIOGRAPHICAL SKETCH FORMAT PAGE

Complete a Biographical Sketch for all **new** senior/key personnel since the previous submission. Follow the biosketch instructions in the competing application guide.

2.5 Other Support

For the purposes of the continuation progress report, other support information is **only** required on **active** support for all senior/key personnel. Include other active support for all senior/key personnel whose support has changed and indicate what the change has been. Refer to the competing application instructions, definitions, policy, and format pertaining to other support. Do not include other supporting information for individuals designated as other significant contributors unless their involvement has changed so that they now meet the definition of senior/key personnel.

2.6 Progress Report Summary

FORM PAGE 5

Well-planned Progress Reports can be of great value by providing records of accomplishments that serve as a basis for continued support of the project. Furthermore, Progress Reports provide information to awarding component staff that is essential in the assessment of changes in scope or research objectives (as defined in the *NIH Grants Policy Statement*) from those actually funded. They

are also an important information source for the awarding component staff in preparing annual reports, in planning programs, and in communicating scientific accomplishments to the public and to Congress.

The Progress Report should be a brief presentation of the accomplishments on the research project during the reporting period, in language understandable to a biomedical scientist who may not be a specialist in the project's research field. The style used in *Scientific American* articles would be appropriate. Abbreviations and language that may not be known to the broader scientific community should be avoided unless clearly defined.

When submitting Progress Reports for program project grants, center grants, education grants, or other large multicomponent grants, contact the program official of the awarding agency for specific instructions.

The entire Progress Report for regular projects, exclusive of the list of publications and the inclusion enrollment report forms **should not exceed two pages.** The report should follow the outline and numbering system shown below. Continuation pages may be used as necessary. Tables and figures that summarize key accomplishments are not counted in the two-page limit.

A. Specific Aims

The aims, **as actually funded**, may differ in scope from those stated in the original, competing application, because of Scientific Review Group (SRG) and Council recommendations and/or budgetary modifications made by the awarding component. If the aims have not been modified, state this. If they have been modified, give the revised aims and the reason for the modification.

B. Studies and Results

Describe the studies directed toward specific aims during the current budget year and the positive and negative results obtained. If applicable, address any changes to the innovative potential of the project. If technical problems were encountered in carrying out this project, describe how the approach was modified.

Revisions (formerly Supplements)

If applicable, include a separate section(s) describing the results obtained by individuals supported on this grant through various revisions. Examples include Research Supplements to Promote Diversity in Health-Related Research, supplements to enhance diversity and Re-entry and/or other similar supplements to support addition of an individual or a discrete project.

C. Significance

Emphasize the significance of the findings to the scientific field and their potential impact on health.

D. Plans

Summarize plans to address the Specific Aims during the next year of support. Include any important modifications to the original plans.

Human Subjects

Complete item A on Form Page 5.

If the clinical studies planned for the coming year are different from those proposed in the previous submission, or if a new applicable clinical study or trial is proposed, include an explanation of how they differ and provide a new or revised Protection of Human Subjects section as described in Part II of the Supplemental Grant Instructions for All Competing Applications and Progress Reports. Include designated headings, as appropriate, for Exempt Human Subjects Research, Non Exempt Human Subjects Research, Clinical Trial, or NIH Defined Phase III Clinical Trial, Data and Safety Monitoring,

Inclusion of Women and Minorities, and Inclusion of Children. New PHS Inclusion Enrollment Report(s) should also be provided if the study meets the NIH definition for clinical research. New studies or study changes will require IRB approval, in accord with the DHHS regulations for protection of human subjects. Provide a protocol only upon request.

If human subject studies planned for the coming year were identified in the Research Plan of the competing application, but were not adequately described because they were planned for a later time within the project period, provide Protection of the Human Subjects and Inclusion sections as well as the PHS Inclusion Enrollment Report(s) as instructed in Part II of the Supplemental Grant Instructions for All Competing Applications and Progress Reports.

If studies involving human subjects are planned, and they were not part of the originally proposed research design, provide a Protection of Human Subjects as instructed in Part II of the Supplemental Grant Instructions for All Competing Applications and Progress Reports, and also provide the following information: whether all of the research is exempt under 45 CFR Part 46, and if so, the exemption number, the Federalwide Assurance number, whether the research is a Clinical Trial and whether the research is an NIH defined Phase III Clinical Trial (see definitions in Part III of the Supplemental Grant Instructions for All Competing Applications and Progress Reports). Also include a section addressing plans for the inclusion of women, minorities, and children and provide PHS Inclusion Enrollment Report(s) as described in Part II of the Supplemental Grant Instructions for All Competing Applications and Progress Reports.

The National Institutes of Health (NIH) Policy on Dissemination of NIH-funded Clinical Trial Information establishes the expectation that all NIH-funded awardees and investigators conducting clinical trials, funded in whole or in part by the NIH, will ensure that their NIH-funded clinical trials are registered at, and that summary results information is submitted to, ClinicalTrials.gov for public posting. This policy applies to grant applications including clinical trials submitted on or after January 18, 2017. The Notice of Award will identify if a grant is subject to this policy.

Additionally, Public Law 110-85, also known as the Food and Drug Administration Amendments Act (FDAAA) of 2007, mandates registration and results reporting of certain “applicable clinical trials” in ClinicalTrials.gov.

Clinical trials must be registered in ClinicalTrials.gov not later than 21 calendar days after the enrollment of the first participant, and results information must be submitted not later than one year after the trial’s primary completion date.

When submitting a non-competing continuation progress report for a project that includes NIH-funded clinical trial(s):

- If the progress report includes *a NIH-funded clinical trial that is registered in ClinicalTrials.gov*, then the Human Subjects section of the progress report must include, under a heading entitled “ClinicalTrials.gov”, the ClinicalTrials.gov registry number (“NCT” followed by an 8-digit number, e.g. NCT00000418) for each trial under the grant. If the grant number was entered into ClinicalTrials.gov when registering, the NCT number may be readily identified by using the ClinicalTrials.gov Advanced Search and entering the grant number in the “Study IDs” field. Each NIH-funded clinical trial should have only one entry in ClinicalTrials.gov that contains its registration and results information. For each trial, also provide the date of enrollment of the first participant and the primary completion date, if available, and indicate whether the trial is an Applicable Clinical Trial under FDAAA.
- Also, under the heading entitled “ClinicalTrials.gov” include the following Clinical Trials Registration and Reporting certification:

- *Certification is hereby provided that the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 days after enrollment of the first participant. Primary summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance.*

In signing the application Face Page, the AOR of the recipient organization certifies that if the research is an applicable clinical trial under Public Law 110-85, the applicant organization will be in compliance with the registration and reporting requirements of Public Law 110-85 (Part III, Section 2.1.6 of the Supplemental Grant Instructions for All Competing Applications and Progress Reports). See the NIH Office of Extramural Research ClinicalTrials.gov web site (http://grants.nih.gov/ClinicalTrials_fdaaa) for additional information.

Inclusion of Women and Miniorities in Clinical Research – Reporting Data on Inclusion to NIH

Unless otherwise notified by NIH staff, reporting the cumulative enrollment of subjects and the distribution by sex/gender, race, and ethnicity is required for NIH-defined clinical research, as defined in the competing application instructions. Update the PHS Inclusion Enrollment Report to reflect the total cumulative enrollment data collected to-date**.**

The progress report may include more than one inclusion enrollment form. If there are details or concerns related to the inclusion enrollment progress or if the enrollment data does not reflect the planned enrollment by sex/gender, race, and/or ethnicity, the explanation(s) for this should be addressed in the text of the progress report. If new clinical studies have started and planned enrollment was not previously provided, submit PHS Inclusion Enrollment Report(s) (also see Section 2.6.D., Plans – Human Subjects above for details on additional information that may be required).

Below are instructions for how to collect and report data on the basis of sex/gender, race, and ethnicity with additional guidance for handling subpopulations, non-U.S. populations, changes to planned enrollment data, and NIH-defined Phase III clinical trials.

For questions about the NIH policies for inclusion, please refer to: http://grants.nih.gov/grants/funding/women_min/women_min.htm or contact the program officer.

Standards for Collecting Data from Study Participants: The Office of Management and Budget (OMB) Directive No. 15 defines minimum standards for maintaining, collecting and presenting data on ethnicity and race for all Federal (including NIH) reporting purposes. The categories in this classification are social-political constructs and should not be interpreted as being anthropological in nature. The standards were revised in 1997 and now include two ethnic categories: Hispanic or Latino, and Not Hispanic or Latino. There are five racial categories: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. Reports of data on ethnicity and race should use these categories. The definitions below apply for the ethnic and racial categories.

Ethnic Categories:

Hispanic or Latino: A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino".

Not Hispanic or Latino

Racial Categories:

American Indian or Alaska Native: A person having origins in any of the original peoples of North, Central, or South America and maintains tribal affiliation or community attachment.

Asian: A person having origins in any if the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.

Black or African American: A person having origins in any of the black racial groups of Africa. Terms such as “Haitian” or “Negro” can be used in addition to “Black or African American.”

Native Hawaiian or Other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

White: A person having origins in any of the original peoples of Europe, North Africa, or the Middle East.

Reporting Data on Race and Ethnicity: NIH is required to use the above standards and definitions for race and ethnicity to allow comparisons to other federal databases, especially the Census and national health databases. Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

When collecting data on ethnicity and race, as well as sex/gender, use the categories listed to obtain the data from individuals on the basis of self-identification. Participants should be asked to identify their ethnicity and their race. The OMB recommends collecting this information using two separate questions, with ethnicity information collected first followed by race, with the option to select more than one racial designation. **The NIH inclusion enrollment format is not designed for use as a data collection instrument.** Collect the data using instruments prepared for the study and use that information to complete the NIH inclusion enrollment form(s). Study participants who self-identify with more than one racial categories should be reported in the aggregate in the "More Than One Race" category.

Collecting and Reporting Data on Subpopulations: Each ethnic/racial group contains subpopulations that are delimited by geographic origins, national origins, and/or cultural differences. It is recognized that there are different ways of defining and reporting racial and ethnic subpopulation data. The subpopulation to which an individual is assigned depends on self-reporting of specific origins and/or cultural heritage. Attention to subpopulations also applies to individuals who self identify with more than one ethnicity or race. These ethnic/racial combinations may have biomedical, behavioral, and/or social-cultural implications related to the scientific question under study. The collection of greater detail is encouraged, e.g., on ethnic/racial subpopulations; however, any collection that uses more detail needs to be organized in such a way that the additional categories can be aggregated into the OMB categories for reporting data on ethnicity, race, and more than one race. Investigators who have data on subpopulations are encouraged to provide that information in the Comments field of the inclusion enrollment form(s) and/or in the text of their progress report.

Collecting and Reporting Data on Participants at Non-U.S. Sites: If conducting NIH-defined clinical research outside of the United States, design culturally appropriate data collection instruments that allow participants to self-identify their ethnic and/or racial affiliation in a way that is meaningful in the cultural and scientific contexts of the study. However, investigators must use the OMB-defined categories for reporting sex/gender, race and ethnicity to NIH (see definitions for each ethnic and racial category above), which will allow completion of the inclusion enrollment forms(s). Since the OMB categories reference world-based geographic origin, this should facilitate completion of the form(s). Enrollment **of participants at non-U.S. sites should be reported to NIH on a separate NIH inclusion enrollment form from that for reporting participants at U.S. sites, even if they are part**

of the same study. For additional guidance and FAQs related to this topic, please refer to: http://grants.nih.gov/grants/funding/women_min/women_min.htm or contact the program officer.

Changes to Planned Enrollment: If there are changes from the planned enrollment originally approved for funding, contact the program officer to discuss updating/revising planned enrollment, address the change in the text of the progress report, and provide the updated PHS Inclusion Enrollment Report(s).

Reporting Data on NIH-defined Phase III Clinical Trials: If conducting an NIH-defined Phase III Clinical Trial, report on the cumulative enrollment (as described above) and indicate if any data analysis has begun for the trial. If analysis has begun or data have been published, report any progress made in evaluating potential differences on the basis of sex/gender, race, and/or ethnicity.

Human Subjects Education Requirement

If there are any new senior/key personnel or other significant contributors involved in the design or conduct of research involving human subjects, provide certification in the Progress Report Summary that they have completed an educational program in the protection of human subjects. This requirement may not apply to other awarding agencies. Non-NIH recipients should contact their awarding agency for guidance (refer to table in Section 1.1).

Vertebrate Animals

Complete item B on Form Page 5.

If vertebrate animals were not involved in the last application but are now to be included, or if significant changes regarding the use of animals are now proposed, provide a description of the intended involvement of animals in accord with the PHS Policy on Humane Care and Use of Laboratory Animals. Examples of changes considered to be significant include, but are not limited to, changing animal species, changing from noninvasive to invasive procedures, new project/performance site(s) where animals will be used, etc. If studies involving live vertebrate animals are planned, and they were not part of the originally proposed research design, you must comply with the requirements of the Research Plan, Item 5.5.10, “Vertebrate Animals,” described in the competing application instructions, and provide the required information. Before activities with live vertebrate animals begin, the applicant must provide a valid Animal Welfare Assurance number and certification of current IACUC approval.

Select Agent Research

Complete item C on Form Page 5. If there are any changes involving use of Select Agents, include an explanation of how research plans differ and provide a new or revised Section 5.5 Select Agent Research of the Research Plan following the competing application instructions, reflecting the changes.

If Select Agent Research planned for the coming year was described in the Research Plan of the competing application, but had not been approved by regulatory authorities, provide the Select Agent Research information requested in the competing application instructions.

If studies involving Select Agents are planned, but were not part of the originally proposed research design, provide Section 5.5 Select Agent Research of the Research Plan following the competing application instructions.

Multiple PD/PI Leadership Plan

This section is only applicable if Multiple PD/PIs are part of the NIH approved project.

Complete item D on Form Page 5.

If there has been any change in the governance and/or organizational structure of the Multiple PD/PI Leadership Plan, provide a description, including communication plans and procedures for resolving conflicts, any changes to the administrative, technical, and scientific responsibilities for the PD/PIs.

If the progress report submission includes a change in the contact PD/PI, address this change and the impact, if any, the change has on the administrative, technical, and scientific responsibilities for the PD/PIs.

Human Embryonic Stem Cell Line(s) Used

Complete item E on Form Page 5.

If the research involving hESCs planned for the coming year is different from that proposed in the previous submission, including use of a different cell line, include an explanation of how research plans differ, and if different cell lines are to be used, provide the cell line number(s). Only cell lines listed on the NIH hESC Registry as approved for use in NIH funded research may be used.

E. Publications

Report publications resulting directly from this grant that you have not previously reported, including manuscripts accepted for publication. (If there are no publications to report, include such a statement.) Using My Bibliography provide a My NCBI generated PDF list of publications (see http://www.nlm.nih.gov/pubs/techbull/nd12/nd12_myncbi_pdf.html for instructions). My Bibliography will display the correct text format, and if available, include the appropriate reference number (PMID, PMCID, or NIHMSID), and compliance status for NIH recipients. If a publication is not compliant with the NIH public access policy NIH staff will contact the PD/PI and business official to inform them that the award will be delayed until a reply to the email is received with evidence of compliance or a satisfactory explanation (e.g., the sole author has passed away before they were able to process the manuscript for posting to PubMed Central). Generally, it takes weeks to bring publications into compliance; therefore, PD/PIs are advised to do so as soon as possible to ensure their award is renewed in a timely manner.

For additional information on compliance with the NIH Public Access Policy and use of My Bibliography see NIH Guide Notices NOT-OD-08-119, NOT-OD-09-136, NOT-OD-10-103, NOT-OD-12-160, and NOT-OD-13-017.

F. Project-Generated Resources

If the research supported by this grant resulted in data, research materials (such as cell lines, DNA probes, animal models), protocols, software, or other information available to be shared with other investigators, describe the resource and how it may be accessed.

If the initial research plan included a formal plan for sharing final research data, describe progress in implementing that plan. A final statement on data sharing should be included in the final progress report or earlier, if the plan is implemented prior to closeout.

If the initial research plan included specifics for sharing model organisms, include information on the progress of that plan as well as information on the number of requests received and fulfilled.

If the initial research plan includes Genome Wide Association Studies and a plan to share data with the NIH centralized data repository, describe progress in implementing that plan. A final statement on submitting data to the repository should be included in the final progress report or earlier, if the plan is implemented prior to closeout (see NOT-OD-08-023 and NOT-OD-07-088).

2.7 Checklist

FORM PAGE 6

Program Income

See the competing application instructions and the *NIH Grants Policy Statement* for information on program income. If no program income is anticipated during the period(s) for which grant support is requested, no other action is necessary.

If program income is anticipated, use the format provided. If the progress report is funded, the Notice of Award will provide specific instructions regarding the use of such income.

Facilities and Administrative Costs

Follow the instructions on the Checklist.

2.8 All Personnel Report

Complete form page 7, and remember to include the PD/PI(s). In addition, list **all other personnel** (salaried and unsalaried) **for the current budget period** at the applicant organization or elsewhere, who participated in the project during the current budget period for at least one person month or more, regardless of the source of compensation. A person month equals approximately 160 hours or 8.3% of annualized effort. Include the Commons ID (when applicable) names of individuals, all degrees, the last four digits of the Social Security number, role on project, date of birth (MM/YY), and number of person months devoted to the project (indicate academic, calendar, and/or summer).

When requesting the last four digits of the Social Security numbers from personnel, explain that provision of the Social Security number is voluntary, and the information will be used only for program management purposes. For progress reports submitted using the PHS 2590, the Commons ID is currently required for all PD/PIs, all individuals with a postdoctoral role, and all individuals supported by a Reentry or Diversity Supplement. For NIH recipients, the Commons ID will be required in the future for all individuals with a graduate student or undergraduate role. The Commons ID is strongly encouraged, but not required, for all other personnel.

Use the following categories for describing Role on Project:

- PD/PI
- Co-Investigator
- Faculty
- Postdoctoral (scholar, fellow, or other postdoctoral position)
- Technician
- Staff Scientist (doctoral level)
- Statistician
- Graduate Student (research assistant)
- Non-student Research Assistant
- Undergraduate Student
- High School Student
- Consultant
- Other (please specify)

If personnel are supported by a Reentry or Diversity Supplement please indicate such after the Role on Project, using the following abbreviations:

- RS - Reentry Supplement
- DS - Diversity Supplement

Individuals designated as “Other Significant Contributors,” (e.g., those that may contribute to the scientific development or execution of the project, but are not committing any specified measurable effort to the project), should **not** be included in this report unless their involvement has changed so that they are now participating in the project during the current budget period for at least one person month or more.

Recipients should not report personnel if they have submitted a 2271 Appointment form for those individuals (e.g., participants on R25 or R90 awards).

This is the last page of the hard copy progress report. Number all pages consecutively.

3. General Information

3.1 Collection of Personal Demographic Data

Federal Agencies have a continuing commitment to monitor the operation of its review and award processes to detect, and deal appropriately with, any instances of real or apparent inequities. In addition, section 403 of the 2007 NIH Reform Act requires NIH to report to Congress specifically on the outcomes and effectiveness of various types of training programs, including training supported through research grants; and section 489 of the PHS Act requires NIH perform a continuing assessment of research personnel needs. Personal demographic data on PD/PIs, students, and postdoctorates working on NIH research projects is vital to comply with these requirements.

NIH collects personal data through the eRA Commons Person Profile. The data is provided one-time by the individual through a secure, electronic system, is private, and is maintained under the Privacy Act record system 09-25-0036, “Grants: IMPAC (Grant/Contract Information).” When completing the data entry in the Commons Personal Profile, the individual is responsible for providing true, accurate, and complete data. Commons IDs are required for individuals holding the following Commons Roles: PI, Undergraduate, Graduate Student, and Postdoctoral. Responses to certain data in the Personal Profiles are now required to meet NIH reporting requirements to Congress. Note in some cases, an acceptable response is “Do Not Wish to Provide.” All analyses conducted on date of birth, citizenship, gender, race, ethnicity, disability, and/or disadvantaged background data will report aggregate statistical findings only and will not identify individuals. For some programs (e.g., Ruth L. Kirschstein National Research Service Awards and Research Career Development Awards) citizenship data is required to determine eligibility.

For AHRQ awards, a Commons ID is required for the PI and individuals in a postdoctoral role only.

The PHS also requests the last four digits of the Social Security Number (SSN) for accurate identification of individuals and for management of PHS grant programs. Please be aware that no individual will be denied any right, benefit, or privilege provided by law because of refusal to disclose this portion of the SSN. The PHS requests the last four digits of the SSN under Sections 301(a) and 487 of the PHS Act as amended (42 U.S.C. 241a and U.S.C. 288).

3.2 Government Use of Information Under Privacy Act

The NIH maintains application and grant records as part of a system of records as defined by the Privacy Act: NIH 09-25-0036, *Extramural Awards and Chartered Advisory Committees (IMPAC 2),*

Contract Information (DCIS), and Cooperative Agreement Information, HHS/NIH: http://oma.od.nih.gov/public/ms/privacy/pafiles/0036.htm .

3.3 Information Available to the Program Director(s)/Principal Investigator(s) (PD/PIs)

Under the provisions of the Privacy Act, program directors/principal investigators may request copies of records pertaining to their grant progress reports from the PHS component responsible for funding decisions. PD/PIs are given the opportunity under established procedures to request that the records be amended if they believe the records are inaccurate, untimely, incomplete, or irrelevant. If the PHS concurs, the records will be amended.

3.4 Information Available to the General Public

The PHS makes information about awarded grants available to the public, including the title of the project, the recipient institution, PD/PI, abstract, and amount of the award.

The Freedom of Information Act and implementing DHHS regulations (45 CFR Part 5) require the release of certain information about grants upon request, regardless of the intended use of the information. Generally available for release, upon request are: all funded grant applications and progress reports including their derivative funded revision application progress reports; pending and funded continuation progress reports; progress reports of recipients; and final reports of any review or evaluation of recipient performance conducted or caused to be conducted by the DHHS. Generally not available for release to the public are: competing grant progress reports (initial, competing continuation, and supplemental) for which awards have not been made; evaluative portions of site visit reports; and summary statements of findings and recommendations of review groups. Trade secrets and commercial, financial, or otherwise proprietary information may be withheld from disclosure. Information, which, if disclosed, would be a clearly unwarranted invasion of personal privacy, may also be withheld from disclosure. Although the recipient institution and the principal investigator will be consulted about any such release, the PHS will make the final determination. If a requested document contains both disclosable and nondisclosable information, the nondisclosable information will be redacted and the balance of the document will be released.

3.5 Access to Research Data

By regulation (45 CFR 74.36), recipients that are institutions of higher education, hospitals, or non-profit organizations are required to provide, in response to a FOIA request, the research data first produced under the award. Research data" is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings. It does not include preliminary analyses; drafts of scientific papers; plans for future research; peer reviews; communications with colleagues; physical objects (e.g., laboratory samples, audio or video tapes); trade secrets; commercial information; materials necessary to be held confidential by a researcher until publication in a peer-reviewed journal; information that is protected under the law (e.g. intellectual property); personnel and medical files and similar files, the disclosure of which would constitute an unwarranted invasion of personal privacy; or information that could be used to identify a particular person in a research study.

These requirements do not apply to commercial organizations or to research data produced by State or local governments. However, if a state or local governmental recipient contracts with an educational institution, hospital or non-profit organization, and the contract results in covered research data, those data are subject to these disclosure requirements.

4. Additional Instructions for Preparing PHS 2590 Continuation Career Development Award (CDA) Progress Reports - Not Applicable to NIH and AHRQ

The instructions in Sections 1-3 are to be used with these additional instructions to request continuation of career development awards (K series) for agencies other than NIH and AHRQ. For all NIH and AHRQ Career Development Awards, use the RPPR instructions at: http://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf.

Awardees should consult the applicable Funding Opportunity Announcement and the awarding Federal agency for any supplemental Instructions.

4.1 Specific Instructions

4.1.1 Detailed Budget for Next Budget Period

FORM PAGE 2

Personnel

Base the awardee's salary and fringe benefits request on a full-time, 12-month appointment following the guidelines in the appropriate career award instructions. Support for other personnel and amounts in other budget categories may be requested in accordance with applicable CDA guidelines.

4.1.2 Biographical Sketch

BIOGRAPHICAL SKETCH FORMAT PAGE

Complete for new senior/key personnel and other significant contributors if allowable under guidelines for the appropriate K award.

4.1.3 Other Support

Provide Other Support information for the career award recipient, sponsor/mentor(s), co-sponsors and senior/key personnel only if changed from the previous submission. For the purposes of the noncompeting continuation progress report, other support information is **only** required on **active** support for these individuals. There is no form page for Other Support. Provide the information in the format shown in the example on the 2590 Forms Page (http://grants.nih.gov/grants/funding/2590/2590.htm).

4.1.4 Progress Report Summary

Follow the instructions for regular research projects found in Section 2.6, Progress Report Summary, using the outline for items A-F. Complete information on human subjects and/or vertebrate animals only if the awardee has participated in research involving human subjects or vertebrate animals that has not been reported within the progress report of any other PHS-supported project. **In addition**, complete Items G-J below. The awardee completes Items G, H, and I; the mentor or supervisor who has the responsibility for the awardee's research career development completes Item J. The Progress Report Summary, including Items G-J, should not exceed four pages.

G. Research Development.

Briefly describe the awardee's involvement in activities during the past year designed to increase research skills. Include formal course work, progress toward a research-related degree (if applicable), informal instruction in specific research skills, scientific seminars and meetings, training in the responsible conduct of research, visits to other laboratories, etc. Describe instruction, or participation as a course director, etc. in the case of senior career awardees, in both formal and informal instruction in responsible conduct of research in the past budget period, if applicable. If instruction, or participation as a course director, etc., occurred in a prior budget period, the PI should note the date of occurrence. Any activities undertaken to individualize instruction appropriate to the career stage of the PI should be discussed. (Additional detailed guidance on this requirement is found in Part III, Section 1.16 of the Supplemental Grant Instructions for All Competing Applications and Progress Reports.) Indicate any changes in senior/key personnel and other significant contributors (department head, sponsor, and collaborators) during the past year.

H. Other Activities.

Briefly describe the awardee's involvement in activities other than research and research training during the past year. Describe activities such as teaching, clinical care, professional consultation, service on advisory groups, and administrative activities. Indicate percent of time spent in each of these activities and the relationship to the awardee's research career development.

For awards that include a requirement to mentor others (e.g., K05 and K24), indicate the percent of time devoted to mentoring activities, individuals mentored during the reporting period, the frequency and kinds of mentoring, financial and other support provided to mentees, and the productivity of the mentoring relationship.

I. Research Development and Other Activities Planned for the Next Year.

Provide information on similar activities (to those provided in Item G and Item H for the past year) planned for the next year. Awardees should provide a timeline for these activities, including plans to apply for subsequent grant support. Recipients of transition awards (e.g., K22, K99) should report on their progress in identifying an independent research position. Additionally, awardees charged with mentoring others (e.g., K05, K24) should provide information describing planned mentoring activities and proposed mentees (e.g., backgrounds, interests, professional levels, etc.) sufficient to evaluate the quality of the mentoring.

J. Mentor's Report.

Prepare a statement assessing the awardee's progress and performance during the past year, both in research and in terms of development into an independent investigator in the area of the award. Include information on the availability of support for the candidate's research project during the next budget segment. For applicable career transition awards (e.g., K22, K99), describe the awardee's efforts to transition into a permanent research position and the sponsor's contributions to that process.

4.1.5 Study Subjects

Provide the number of human subjects **only** if the career awardee has participated in research involving human subjects that has not been reported within the Progress Report of any other PHS-supported project.

4.1.6 Checklist

FORM PAGE 6

Facilities and Administrative (Indirect) costs on career awards will be awarded at 8 percent of modified direct costs.

4.1.7 All Personnel Report

Complete form page 7, including the awardee and mentor(s), if applicable, and any other individual with one person month effort or more.

This is the last page of the progress report; number all pages consecutively.

5. Additional Instructions for Preparing a Progress Report for an Institutional Research Training Grant, Including Ruth L. Kirschstein National Research Service Awards - Not Applicable to NIH and AHRQ

Progress reports to continue support of a PHS Institutional Ruth L. Kirschstein National Research Service Award (Kirschstein-NRSA) or non-NRSA research training grant to any agency other than NIH and AHRQ must be submitted on PHS 2590 forms. For all NIH and AHRQ NRSA or non-NRSA research training grants, use the RPPR instructions at: http://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf.

The due date for these progress reports is determined by the awarding agency. Recipients access a website to determine when progress reports are due. The Office of Policy for Extramural Research Administration, OER, National Institutes of Health (NIH) hosts the website located at: http://era.nih.gov/commons/quick_queries/index.cfm#progress. Recipients are responsible for periodically checking the list, which is updated on/around the 30th of each month. In addition to this website, e-mail reminders are sent to the PI.

For recipient institutions and PIs registered in the eRA Commons, the progress report due information is available in the Commons Status system. Commons-registered institutions and PIs also have access to pre-populated face pages for the PHS 2590 Progress Report via Status. For more information on the Commons, see: https://commons.era.nih.gov/commons/index.jsp.

This section contains additional instructions, a substitute budget page, Trainee Diversity Report page and Trainee Report Tables 12A and 12B to be used to request continuation (noncompeting) support under the PHS institutional Kirschstein-NRSA as well as non-NRSA programs. Follow both sets of instructions in preparing the progress report only if the non-NIH agency has provided guidance to do so.

5.1 Specific Instructions

5.1.1 Face Page

Items 1-5.

Follow instructions (Items 1-5).

Item 6. Human Subjects

In many instances, trainees supported by institutional training grants will be participating in research projects for which the Institutional Review Board (IRB) review of human subjects is complete or an exemption is designated. This review or exemption designation is sufficient, providing the research would not be substantially modified by participation of a trainee. The appropriate grants must be identified along with their IRB review dates or exemption designation. If space is insufficient in Item 6a, indicate "Next Page" and provide the information on a plain sheet of paper after the Face Page.

If the applicant organization has an approved Federal Wide Assurance or Multiple Project Assurance on file with the Office for Human Research Protections (OHRP) but, at the time of progress report, plans for the involvement of human subjects are so indefinite that IRB review and approval are not feasible, check "Yes" and insert "Indefinite" at Item 6a. If an award is made, human subjects may **not** be involved until a certification of the date of IRB approval, or a designation of exemption, has been submitted to the PHS awarding component.

Item 7. Vertebrate Animals

In many instances, trainees supported by institutional training grants will be participating in research projects for which the Institutional Animal Care and Use Committee (IACUC) review is complete. This review is sufficient, providing the research would not be substantially modified by participation of a trainee. The appropriate grants must be identified along with the current IACUC review dates. IACUC approval must have occurred within the past three years to be considered current. If space is insufficient in Item 7, indicate "Next Page" and provide the information on a plain sheet of paper after the Face Page.

Check "Yes" and insert "Indefinite" at Item 7 if the applicant organization has an approved Animal Welfare Assurance on file with Office of Laboratory Animal Welfare (OLAW), but at the time of progress report, plans for the involvement of vertebrate animals are so indefinite that IACUC review and approval are not feasible. If an award is made, vertebrate animals may **not** be involved until a verification of the date of IACUC approval has been submitted to the PHS awarding component.

The institution must ensure that trainees are enrolled in the institution’s animal welfare training and occupational health and safety programs for personnel who have contact with animals, as appropriate. It is also the institution’s responsibility to ensure that trainees are properly supervised when working with live vertebrate animals.

Item 9. Inventions and Patents

Not applicable.

Item 13. Applicant Organization Certification and Acceptance

For Kirschstein-NRSA institutional training grants, the signature of the official signing on behalf of the institution also assures that postdoctoral trainees have been informed of payback requirements associated with the Kirschstein-NRSA program.

5.1.2 Next Budget Period

FORM PAGE 2

The policy concerning tuition, fees and health insurance for Kirschstein-NRSA training grants is described in NOT-OD-16-062. **For non-NRSA training grant programs, refer to the FOA for instructions about budget reporting.**

Use the Kirschstein-NRSA substitute budget page, and follow the instructions below, to request direct costs for the next budget period. Any additional information should be provided on Form Page 3.

Stipends

Enter the number of trainees and stipend amount for each trainee. Identify, by name, all trainees to be continued and new trainees to whom a commitment has been made for the next budget period.

Tuition and Fees (excluding Health Insurance)

Institutions are referred to the policy for funding of tuition, fees, and health insurance at NOT-OD-16-062.

In this category, itemize tuition and individual fees only. If tuition varies (e.g., in-state, out-of-state, student status, or dual-degree program), identify these separately. Tuition at the postdoctoral level is limited to that required for specified courses. Tuition and fees may be requested only to the extent that the same resident or nonresident tuition and fees are charged to regular non-Federally-supported students and postdoctoral fellows.

Trainee Travel

State the purpose of any travel; give the number of trips involved, the destinations, and the number of individuals for whom funds are requested. Justify foreign travel in detail, describing its importance to the training experience.

Training Related Expenses (including Health Insurance)

Funds to defray other costs of training, such as health insurance (self-only or family, as applicable), staff salaries, consultant costs, equipment, research supplies, staff travel, etc., are requested as a lump sum based on the predetermined amount per predoctoral and postdoctoral trainee. Enter the total dollar figure only.

While health insurance is included as part of this category and will be awarded as a lump sum based on the new policy, the actual costs of applicable self-only or family health insurance for potential trainees should be separately identified in the budget.

5.1.3 Budget Justification

FORM PAGE 3

Indicate whether all stipends awarded for the current budget period will be used and explain any estimated unexpended balance. Explain any rebudgeting from trainee positions (stipends) into tuition and fees that has occurred in the current budget period, including the number of trainee positions (predoctoral and postdoctoral) and the estimated dollar figure that was rebudgeted during the budget period being reported. In addition, if rebudgeting is planned in the upcoming budget period, include similar information on those plans as well.

5.1.4 Biographical Sketch

BIOGRAPHICAL SKETCH FORMAT PAGE

Provide biographical sketches **only** for newly added training faculty.

5.1.5 Other Support

Not applicable.

5.1.6 Progress Report Summary

FORM PAGE 5

Use the following instructions to prepare a progress report, which provides a presentation of the accomplishments and changes in the training program during the reporting period, following the outline below: For recipients submitting the first progress report since award of a grant renewal, the reporting period should include all months since submission of the renewal application.

A. Training Program

1. Provide a description of the training objectives and goals for the reporting period. Highlight progress in implementation and developments or changes that have occurred. Note any difficulties encountered by the program. Describe changes in the program for the next budget period, including changes in training faculty and significant changes in available space and/or facilities. Include, as appropriate, a description of how the following elements aid in strengthening and realizing the objectives and goals of the program:
    - the external advisory committee(s),
    - any significant new training content, procedures or experiences,
    - NIH recipients: the use of Individual Development Plans (IDPs) in managing the training of predoctoral and postdoctoral trainees. (Actual IDPs should not be included; see NOT-OD-14-113 and NOT-OD-13-093 for additional information.)
2. Describe the nature of the instruction in the responsible conduct of science and the extent of trainee and faculty participation during the last budget period. Include a description of any enhancements and/or modifications to the five instructional components from the plan described in the awarded application. Specific training faculty members who were contributors to formal instruction in responsible conduct of research during the last budget period must be named. (Additional detailed guidance on this requirement is found in Part III, Section 1.16 of the Supplemental Grant Instructions for All Competing Applications and Progress Reports.)
3. Describe activities related to recruitment and retention of trainees from diverse groups.
4. If trainees took part in research involving select agents with faculty participating in the training program, address the requirements described in Section 2.6.D., Plans – Select Agent Research.

B. Study Subjects

Provide data using the inclusion enrollment form(s) (described in Section 2.6.D., Plans – Human Subjects above) only if the trainees have participated in research involving human subjects that has not been reported within the progress report of another PHS-supported project.

C. Trainees

1. Update the data on trainees supported by the training grant in Table 8A, 8B, and/or 8C , as applicable, to reflect new appointments and other changes that have occurred over the reporting period. For trainees who have left the program, and those trainees who have completed their training during this reporting period, indicate the degree earned and the nature of their current positions. Include the name of the institution, type, research involvement, and any other relevant information. Do not include data that is more than 10 years old.

   Recipients with NIH institutional training grant awards with specified activity codes are required to provide program statistics in Table 8A, indicating the percentage of students admitted for study who successfully attain a doctoral degree, and the average time between the beginning of graduate study and the receipt of a doctoral degree (not including any leaves of absence). NIH activity codes affected by this requirement are: D43, TU2, T15, T32, T37, T90, U2R, U90, and U54/TL1.

2. Use the Trainee Diversity Report format page to report on the diversity of the trainees supported by this grant during the reporting period. Enter the Grant Number including support year reported, the Training Grant Title, and Total Number of Trainees Appointed during the reporting period. In Part A of the report, indicate for **all** trainees the numbers that fall into each ethnic and racial category. The number of multi-racial trainees will be entered into the row "more than one race." Normally, the unknown or not-reported categories will not be needed.

   In Part B of the report, indicate for "Hispanic or Latino" trainees the numbers that fall into each racial category. In Part C of the report, indicate the number of Trainees with Disabilities or are from Disadvantaged Backgrounds. Definitions of the indicated racial and ethnic categories are described in the competing application instructions.

3. Include a paragraph that describes the research project and course work of each trainee supported during the reporting period, as well as any conference presentations, honors, fellowships, etc.

4. List the titles and complete references (author(s), journal or book, year, page number) of all trainee publications **not previously reported**, including those by former trainees still in research training. This includes manuscripts submitted or accepted for publication.

Peer-reviewed trainee publications that arise from support of the training grant must be reported in accord with Section 2.6.E., Publications above. It will be necessary for the Program Director to add trainee publications to his/her MyBib so that a list of these publications is appropriately generated. Trainee publications may be placed in the section entitled "Other Publications" in MyBib. My Bibliography will display the correct text format, and if available, include the appropriate reference number (PMID, PMCID, or NIHMSID), and compliance status for NIH recipients.

Citations that are not covered by the NIH Public Access Policy but are publicly available in a free, on-line format may include URLs or the PubMed Central numbers (PMCID) along with the full reference.

5.1.7 Checklist

FORM PAGE 6

Facilities and Administrative (Indirect) Costs

Facilities and Administrative (F&A) costs under institutional Kirschstein-NRSAs, other than those issued to State or local government agencies, will be awarded at 8 percent of total modified direct costs (excluding the tuition/fees category and sub-grants and contracts in excess of $25,000). Equipment is also excluded on those training grants where Training Related Expenses are not calculated on a lump-sum basis, such as the MARC or COR Honors Undergraduate Research Training Grants. The treatment of health insurance will vary according to the policies under which a Kirschstein-NRSA award was made (for details, see Item 2). State and local government agencies will receive awards at their full Facilities and Administrative cost rate.

5.1.8 All Personnel Report

FORM PAGE 7

Not applicable.

6. Additional Instructions for Preparing a Progress Report for an SBIR/STTR Award - Not Applicable to NIH and AHRQ

For SBIRs/STTRs awarded by NIH, use the RPPR instructions at: http://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf.

AHRQ does not issue SBIR/STTR awards.

For SBIRs/STTRs awarded by other agencies, follow the instructions in Sections 1 and 2 of this document. Additionally, all SBIR and STTR progress reports must include the following information:

What is the impact on technology transfer?

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- transfer of results to entities in government or industry;
- instances where the research has led to the initiation of a start-up company; or
- adoption of new practices.

Commercialization Activities

Report on the status of commercialization activities resulting from the award:

- Nothing to report or select one or more of the following:
- Sales = $_____
- Licensing revenue = $_____
- 3rd Party investment since award start (Non-federal) = $_____
- Sale of company
- Sale of technology rights

- Company merger related to product
- Joint venture agreement
- Marketing/Distribution agreement(s)
- Manufacturing agreement(s)
- R&D agreements
- Customer alliance(s)
- Other _____ [60 character limit]

FDA Interactions

Report on interactions with the Food and Drug Administration during the reporting period related to the technology that is the subject of the award:

- Not applicable to this technology or select one or more of the following:
- Discussion with FDA not initiated
- Discussion with the FDA initiated
    - Approval in Progress
        - Applied for approval
        - Review ongoing
        - In human clinical trials
        - Other_____
    - Approval Granted: Type _____
    - Not approved

6.1 SBIR/STTR Fast-Track Phase II Applications

An SBIR/STTR Fast-Track Phase II application may be funded following submission of an original PHS 2590 Non-competing Continuation Progress Report. Funding for the Phase II application will be contingent upon (1) assessment of the Phase I progress report and determination that the Phase I goals and milestones were achieved; (2) an update (as necessary) of the Commercialization Plan; (3) determination of the project's potential for meeting the mission of the awarding component and for commercial success; (4) review and approval of other documents necessary for continuation; and (5) availability of funds.

The grants management and program staff of the awarding IC will review the SBIR/STTR Fast-Track Phase II application. If the continuation request is not approved, then written notification will be sent to the applicant.

To complete the SBIR/STTR Fast-Track Phase II application, follow the directions under Sections 1 and 2 of this document, with the following exceptions:

1. The PHS 2590 should be submitted in accordance with the instructions in the terms and condition of award found on the Notice of Award.
2. The research plan, should include the following information:
    a. A Phase I Final Progress Report: Follow the application instructions in the General Application Guide for NIH and Other PHS Agencies, Research Plan Form, Item 3, Research Strategy, Progress Report for Phase II and Phase II Competing Renewal and Revision Applications at http://grants.nih.gov/grants/how-to-apply-application-guide.htm.
    b. A section labeled Milestones (l) identifying either the milestones described in the original Phase I application as approved by the peer reviewers or the milestones modified by the

peer reviewers and negotiated with the recipient; and (2) describing the progress achieved relative to the milestones.

c. A one-page abstract describing the research plan for Phase II. See 2.6. D, Plans of the Progress Report Summary section. If the aims have not been modified from the original Phase II application, state this. If they have been modified, give the reviewed aims and the reason for the modifications.

d. An updated Commercialization Plan as necessary, if changes have been made from the original submission.

3. Include answers to the following questions:

a. Will there be, in the next budget period a significant change in the level of effort for the PD/PI or other Senior/Key Personnel designated on the Notice of Award from what was approved for this project?

If yes, please explain (e.g., decreased level of effort from 4.8 calendar year (CY) months to 3.6 CY months); if no, so state. A significant change in level of effort is defined in Federal regulations as a **25 percent reduction** in time devoted to the project, from what was approved at the time of award. For example, if a NoA-specified individual on the project is expected to reduce his/her effort from 4.8 CY months to 3.6 CY months, which represents a 25 percent reduction in the level of effort, an explanation must be provided.

b. Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25% of the current year's total approved budget?

The total approved budget equals the current fiscal year award authorization plus any approved carryover of funds from a prior year(s). The numerator equals the total amount available for carryover and the denominator equals the current year's total approved budget.

If yes, provide the estimated unobligated balance and an explanation for the unobligated balance.