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

Non-Competing Grant Progress Report (PHS 2590)

Instructions for PHS 2590
Revised 09/2004

Forms Approved Through 09/30/2007
OMB No. 0925-0001

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IMPORTANT CHANGES

This version of the PHS2590 incorporates applicable policy changes implemented since the 5/01 version. In addition, the following changes are highlighted:

- Information has been included on the new business process – centralized receipt of progress reports.
- The submission requirement has been changed – grantees need only submit a signed original and **one** signed copy.
- Information has been included promoting the use of the E-SNAP system in the eRA Commons.
- The SNAP Instructions have been rewritten to clarify which mechanisms are generally included in SNAP. For SNAP Question #1, **complete** Other Support is now required when changes are reported. For SNAP Question #2, the wording has been modified to make it clear that the applicability is only for the PI and other personnel specifically designated on the Notice of Grant Award.
- Throughout the instruction, the refined definition of Key Personnel has been incorporated.
- The new category "Other Significant Contributors" has also been incorporated throughout the instructions.
- SBIR and STTR Instructions have been added for progress report submission.
- On the Key Personnel Report, the request for a Social Security Number is now limited to the last four digits.

I. SUBMITTING YOUR PROGRESS REPORT

Progress reports to continue support of a PHS grant must be **submitted two months** before the beginning date of the next budget period using the PHS 2590. All progress reports must now be submitted **to the centralized mailing address:**

Division of Extramural Activities Support, OER
National Institutes of Health
6705 Rockledge Drive, Room 2207, MSC 7987
Bethesda, MD 20892-7987 (for regular or US Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express mail delivery only)
Phone Number: (301) 594-6584

Submit the completed, signed original progress report and one copy (with required signatures).

Note this is a change in business process. Progress reports should no longer be submitted directly to the NIH awarding component. For additional information on this process change, see the NIH Guide Notice OD-04-063: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-063.html.

Grantees access a website to determine which 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/userreports/pr_due.cfm. Grantees 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 grantee 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 2590 Progress Report via Status. For more information on the Commons, see:

https://commons.era.nih.gov/commons/index.jsp.

Additional information on this notification process can be found in the NIH Guide Notice OD-03-054: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-054.html.

Please note that additional instructions for preparing continuation progress reports for Career Development Awards are found in Section IV and additional instructions for preparing progress reports for Institutional National Research Service Awards are found in Section V.

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. Future developments in electronic transfer of progress reports will be published periodically in the *NIH Guide for Grants and Contracts*. Investigators are encouraged to retain these instructions for future submissions.

Use English only and avoid jargon and unusual abbreviations. Prepare the progress report single-sided and single-spaced, staying within the margin limitations indicated on the form. **NIH now requires the use of Arial or Helvetica 11-point.** 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 readily legible.

Do not bind or staple the original. An incomplete or incorrectly prepared continuation progress report may result in a delay in award of funds.

Electronic Submission of SNAP Progress Reports (eSNAP)

Grantee Institutions registered in the eRA Commons have the ability to electronically submit SNAP progress reports. This system provides grantees the ability to enter data into forms as well as upload files for the progress report and other supporting documentation. For more information on eSNAP, visit the eRA Commons at: https://commons.era.nih.gov/commons/index.jsp.

GrantsInfo, DEOIR, OER, National Institutes of Health

The Division of Extramural Outreach and Information Resources (DEOIR) is the central source for general information about NIH extramural research and research training programs, funding mechanisms, the peer review system, and progress report procedures. The NIH grants Web site is at http://grants.nih.gov/grants/oer.htm. The e-mail address is: GrantsInfo@nih.gov. The phone number is (301) 435-0714.

PHS estimates that it will take approximately 15 hours to complete this progress report for a regular research project grant. Items such as human subjects are cleared and accounted for separately, and are not part of the time estimate for completing this form. 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. If you have comments regarding the burden estimate or other aspect of the collection of information, including suggestions for reducing the burden, send comments to: NIH, Project Clearance Office, 6705 Rockledge Drive MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0001). Do not send progress reports to this address.

II. PREPARING YOUR PROGRESS REPORT

A. Streamlined Noncompeting Award Process (SNAP)

The NIH has developed this simplified process for the submission of information prior to the issuance of a noncompeting award. For additional information on completing any part of PHS 2590, refer to the Specific Instructions (Section B). When additional information is required, use the appropriate form page. For example, the biographical sketch page is still required for new key personnel and/or new other significant contributors.

These simplified instructions apply to all R series grant mechanisms except for Outstanding Investigator Grants (R35s), Phase 1 Small Business Innovation Research Grants (R43) and Phase 1 Small Business Technology Transfer Grants (R41). For Phase I SBIR/STTR awards that *exceed* one year, grantees should review the Notice of Grant Award to determine if their project is subject to or excluded from the SNAP provisions. Career award mechanisms (Ks) are also routinely covered under SNAP. Those mechanisms routinely excluded from SNAP are generally those that do not have the authority to automatically carry over unobligated balances (centers, cooperative agreements, Kirschstein-NRSA institutional training grants, non-Fast Track Phase I SBIR and STTR awards), clinical trials (regardless of mechanism), Program Project Grants (P01s) and Outstanding Investigator Grants (R35s). All NIH award notices identify whether the grant is subject to or excluded from SNAP.

SNAP Instructions for Submitting the Progress Report

Complete Face Page (**Form Page 1**, **MS Word or PDF**) except for items 8a and 8b, the Progress Report Summary (**Form Page 5**, **MS Word or PDF**), and the Key Personnel Report (**Form Page 7**, **MS Word or PDF**). Complete the Checklist Page (**Form Page 6**, **MS Word or PDF**) only if there is a change in performance site(s) that will affect facilities and administrative costs *and/or if program income is anticipated*. If program income is anticipated, the Checklist should reflect the amount and source(s). The Progress Report should begin on Form Page 5. Complete all information and provide a brief, two-page progress report following the instructions for Progress Report Summary. Tables and figures that summarize key accomplishments are not counted in the two-page limit.

For those preparing continuation CDA progress reports under SNAP, use the SNAP instructions found in this section and the additional abbreviated instructions found in Section IV, which includes Items A.4 through A.7.

Answer the following questions at the beginning of Form Page 5. Blank pages should be used for the Progress Report if inadequate space remains on Form Page 5 to answer the questions and to begin the report on the research progress. The questions to be addressed are as follows:

Has there been a change in the other support of key personnel since the last reporting period?

If yes, explain the change(s); if no, so state. Specific information is to be provided only if active support has changed. If a previously active grant has terminated and/or if a previously pending grant is now active, **submit complete Other Support information** using the suggested format and instructions found in the PHS 398 application (MS Word or PDF). Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary if support is pending or for changes in the level of effort for active support reported previously. Other support information should be submitted only for the principal investigator and for those individuals considered by the principal investigator to be key to the project. Key personnel are defined as individuals who contribute in a substantive measurable way to the scientific development or execution of the project, whether or not a salary is requested.

Do not routinely include Other Support information for "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. However, if the level of involvement for an individual previously listed in this category has changed such that they are now considered "key personnel," this change should be indicated in this section and Other Support information submitted.

Will there be, in the next budget period, a significant change in the level of effort for the PI or other personnel designated on the Notice of Grant Award from what was approved for this project?

If yes, please explain (e.g., decreased level of effort from 40 to 30 percent); 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. For example, if a NGA-specified person on the project is expected to reduce his/her effort from 40 percent to 30 percent, which represents a 25 percent reduction in the level of effort, an explanation must be provided at the beginning of the Progress Report Summary (Form Page 5).

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

If yes, please provide an explanation; if no, so state. An explanation should include why there is a significant balance and how it will be spent if carried forward into the next budget period.

Program or grants management staff may require additional information in order to evaluate the project for continued funding. Failure to provide this information will result in a delayed award.

If a project or grantee organization requires closer monitoring by NIH staff, the project or organization may not use these simplified instructions.

If you have any questions, contact the grants management specialist identified on the current Notice of Grant Award.

B. Specific Instructions

1. FACE PAGE

Items 1-5.

The computer-generated Face Page available in the eRA Commons has information already preprinted through Item 5. Complete and use this as the final copy. Add the electronic mail address information, if applicable. Check the preprinted material carefully and, when necessary, make corrections by entering the item number and the correct information under Item 12. Do **not** use Item 12 to indicate change of applicant organization. Form PHS 398 **must** be used in such cases. **Contact the awarding component for further instructions.**

Note: If the preprinted copy is not provided, or extensive corrections are necessary, use PHS 2590 Form Page 1, which is available in MS Word or PDF format.

Item 5. Administrative Official

If the institutional representative to be contacted for additional information has changed, make the necessary corrections in Item 12 on the computer-generated Face Page. Provide the name, telephone, and fax of the administrative official in Item 11b.

Item 6. Human Subjects

Policy on research involving human subjects can be found in the *NIH Grants Policy Statement* or the PHS 398 application instructions (MS Word or PDF). Definitions and guidance pertaining to Human Subjects Research, including clinical trials, may be found in Part II of the PHS 398 (MS Word or PDF). 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, whether or not exempt from the Federal regulations for the protection of human subjects, are planned **at any time** during the budget period, either at the applicant organization or at any other performance site or collaborating institution.

Appropriately designating whether human subjects are involved or not 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 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 PHS 398 application instructions (MS Word or PDF) **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 the planned activities involving human subjects are not exempt, complete the remaining parts of Item 6. If the applicant organization has an approved Human Subjects 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.**

Check the type of IRB review in the appropriate box. An IRB of an institution with an FWA or MPA may review a progress report through an expedited review procedure only if it complies with Section 46.110 of the human subject regulations at 45 CFR Part 46.

Item 7. Vertebrate Animals.

Policy on research activities involving vertebrate animals can be found in the *NIH Grants Policy Statement* or the PHS 398 application instructions (MS Word or PDF). 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 performance site or collaborating institution. Insert the Animal Welfare Assurance number in Item 7b if the applicant organization has an approved Assurance on file with the Office of Laboratory Animal Welfare (OLAW). In addition, provide the latest date of approval by the Institutional Animal Care and Use Committee (IACUC). (Note, PHS policy requires that the IACUC conduct continuing review of activities at least every three years.) **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 **(MS Word or PDF)**.

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 applicant 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 grantee is encouraged to submit reports electronically using Interagency Edison (http://www.iedison.gov). Inquiries or correspondence should be directed to:

Extramural Inventions and Technology Resources Branch
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. Performance Sites

Indicate where the work will be conducted. If there is more than one performance site, list all the sites, including VA facilities and foreign sites. Additional continuation pages may be used, as necessary, immediately following the Face Page. Number the pages consecutively.

Item 11. Telephone and Fax Information

Self-explanatory.

Item 12. Face Page Corrections and Changes

Use this space for corrections and changes.

Item 13. Principal Investigator/Program Director Assurance

An original signature, in ink, is required. “For” or “Per” signatures are not acceptable. Date of signature must be included.

Item 14. Applicant Organization Certification and Acceptance

An original signature, in ink, is required. “For” signatures are acceptable; i.e., if the official designated to sign for the applicant organization is not available to sign, only another institutional official with formal delegated authority to act in his/her behalf may sign as "acting for" such official. However, “Per” signatures (signing as the designated official or without the formal delegation) are not acceptable. The date of signature must be included. In signing the Face Page, the duly authorized representative 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 grantee 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 certifications be verified by the signature of the Official Signing For Applicant Organization on the Face Page of the progress report.

Definitions are provided in the *Grants Policy Statement* and in the PHS 398 application instructions (MS Word or PDF).

- Human Subjects
- Research Using Human Embryonic Stem Cells
- Research on Transplantation of Human Fetal Tissue
- Women and Minority Inclusion Policy
- Inclusion of Children Policy
- Vertebrate Animals
- Debarment and Suspension
- Drug-Free Workplace
- Lobbying
- Delinquent Federal Debt
- Research Misconduct
- Civil Rights
- Handicapped Individuals
- Sex Discrimination
- Age Discrimination
- Financial Conflict of Interest (except Phase I SBIR/STTR)
- Recombinant DNA and Human Gene Transfer Research
- Prohibited Research
- Certification of Research Institution Participation (STTR only)

2. Detailed Budget for Next Budget Period

(FORM PAGE 2, MS Word or PDF)

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 Grant 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 multiproject grants whose individual projects are budgeted separately, additional copies of Form Page 2 (MS Word or PDF) 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 principal investigator, list all employees of the applicant organization who will be involved on the project, regardless of whether or not salaries are requested.

Type of Appointment/Months. List the number of months per year reflected in an individual's contractual appointment to the applicant organization. Unless otherwise noted, PHS staff assume that appointments at the applicant organization represent 12 months/100 percent time for each individual. If an appointment is less than full time, e.g., 50 percent time, identify with an asterisk (*) and provide a full explanation under Justification on Form Page 3. Individuals may have consecutive appointments within a calendar year, for example for an academic period and a summer period. In this case, for each appointment, identify and enter the number of months on separate lines. In cases where no contractual appointment exists with the applicant organization and salary is requested, enter the number of months for that period.

Percent of Effort on Project. For each individual at the applicant organization, list the percent of each appointment to be spent on this project.

Salary Requested. Enter the dollar amounts for each position for which funds are requested. The salary requested is calculated by multiplying the individual's base salary, **up to any imposed salary limitation**, by the percent of effort on the project. Grantees are encouraged to check the NIH Guide for Grants and Contracts for this topic each year. Explain under Justification on Form Page 3 if a lesser amount is requested, e.g., endowed position, institutional sources, or other support.

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 Appointments

Individuals may request the university's share of the salaries in proportion to the effort devoted to the research project. The individual's salary with the university determines the base for computing that salary request. Signature by the institutional official on the progress report 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 Department of Veterans Affairs (VA); and (2) there is no possibility of dual compensation for the same work, or an actual or apparent conflict of interest regarding such work.

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 and the number 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 by 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 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 by 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.* Costs for alterations and renovations are not allowed on grants made to foreign organizations.

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, MS Word or PDF) and budget justification (Form Page 3, MS Word or PDF) for the next budget period. If a new consortium is added, follow the guidelines in the PHS 398 application instructions (MS Word or PDF).

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.

3. BUDGET JUSTIFICATION

(FORM PAGE 3, MS Word or PDF)

Justification. Provide a detailed budget justification for those line items and amounts that represent a significant change from that previously recommended.

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 authorization. Explain why there is a significant balance and how it will be spent if carried forward into the next budget period.

4. BIOGRAPHICAL SKETCH

(BIOGRAPHICAL SKETCH FORMAT PAGE, MS Word or PDF)

Complete a Biographical Sketch for all **new** key personnel since the previous submission.

> Key personnel are defined as, and should be limited to, individuals who contribute in a substantive measurable way to the scientific development or execution of the project, whether or not salaries are requested.

Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level should be included if their involvement meets the definition of key personnel. Consultants should be included only when their level of involvement meets the definition. Individuals providing technical services are not considered key personnel.

Complete a Biographical Sketch for all **new** "Other Significant Contributors." These individuals are typically those that may contribute to the scientific development or execution of the project, but are not committing any specified measurable effort to the project.

5. OTHER SUPPORT

For the purposes of the noncompeting continuation progress report, other support information is **only** required on **active** support for all key personnel. Refer to the PHS 398 application (MS Word or PDF) for the 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 key personnel.

6. PROGRESS REPORT SUMMARY

(FORM PAGE 5, MS Word or PDF)

Well-planned Progress Reports can be of great value by providing records of accomplishments, which 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 in the awarding component for specific instructions.

The entire Progress Report for regular projects, exclusive of the list of publications and the "Inclusion Enrollment Report," **should not exceed two pages.** The report should follow the outline and numbering system shown below. Continuation pages may be used as necessary.

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 results obtained. Include negative results. If technical problems were encountered in carrying out this project, describe how your approach was modified.

Supplements: If applicable, include a separate section(s) describing the results obtained by individuals supported on this grant through various supplements. Examples include a Research Supplement to Underrepresented Minorities, a Research Supplement to Promote the Recruitment of Individuals with Disabilities into Biomedical Research Careers, 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. Address any changes involving research using human embryonic stem cells, human subjects, and/or vertebrate animals.

Complete Items A and B on Form Page 5 if the research involves Human Subjects or Vertebrate Animals. **If "Change" is checked, provide the information below.** Although no specific page limitation applies to the

information on Human Subjects or Vertebrate Animals, be succinct.

Human Subjects (Item A)

Check "No Change" on the Progress Report Summary page (Form Page 5) if the protocols planned for the coming year are not different from the previous submission.

Check "Change" on the Progress Report Summary page if the protocols are different from those proposed in the previous submission. Include an explanation of how they differ and provide a new or revised Section E. "Human Subjects" from the PHS 398 instructions reflecting these changes; use the designated headings for Non Exempt or Exempt Human Subjects Research, as appropriate, including "Protection of Human Subjects," "Exempt Human Subjects Research," "Women and Minority Inclusion in Clinical Research," "Inclusion of Children," and "Data and Safety Monitoring Plan." New Protocols or Protocol changes will require IRB approval, in accord with the DHHS regulations for protection of human subjects. Provide a protocol upon request.

If human subject studies planned for the coming year were identified in the Research Plan of the PHS 398 application, but were not adequately described because they were planned for a later time within the project period, provide the "Human Subjects" information from the PHS 398 instructions (MS Word or PDF) as noted above.

If studies involving human subjects are planned, and they were not part of the originally proposed research design, then you must comply with the requirements of Section E. "Human Subjects" described in the PHS 398 instructions (MS Word or PDF) and provide the required information to NIH.

Women and Minority Inclusion in Clinical Research

Reporting Data on Inclusion to NIH:

If you are conducting clinical research (see definition in the PHS 398), you must report the annual cumulative enrollment of subjects and their distribution by sex/gender and ethnicity/race, unless otherwise notified by your program official. For awards made as a result of New and Competing applications submitted after January 10, 2002, you should be using the **Inclusion Enrollment Report** (MS Word or PDF) in progress reports. For awards made as a result of New and Competing Applications received before January 10, 2002, you may choose to report sex/gender and ethnicity/race composition using EITHER the format in the **4/98 Version of the Inclusion Table** (MS Word or PDF) or the **Inclusion Enrollment Report** (MS Word or PDF). If data were collected using two questions (one about ethnicity and one about race) and subjects were given the option of selecting more than one race, then the Inclusion Enrollment Report (MS Word or PDF) should be used. If you choose to report information using the Inclusion Enrollment Report, you must continue to use this format for the remaining years of the project. See detailed instructions and frequently asked questions in http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html.

Note: Reporting data on inclusion is not included in the two-page limit. If there is more than one study, provide a separate table for each study. Information about ethnic/racial subpopulations included in the study should be provided as an attachment to the table.

Changes to Targeted/Planned Enrollment. If there are changes from the Targeted/Planned Enrollment originally approved for funding, you should submit a revised Targeted/Planned Enrollment page (MS Word or PDF) and an inclusion enrollment report (MS Word or PDF) describing data collected to-date. Explain the changes in a footnote or attachment to the report.

NIH-defined Phase III Clinical Trial. If you are conducting an NIH-defined Phase III Clinical Trial (see definition in the PHS 398), you must report on the annual cumulative enrollment (as described above) and indicate if data analysis has begun for the trial. If so, you should report on progress made in conducting valid analyses for sex/gender and ethnic/racial differences.

Foreign Populations: If you are conducting clinical research outside of the US, you should design culturally sensitive and appropriate data collection instruments that allow participants to self-identify their ethnic and racial affiliation. These items, however, should be designed in a way that allows you, the investigator, to aggregate the information into the OMB minimally required ethnic and racial categories and complete the Inclusion Enrollment report. When completing the Inclusion Enrollment report, you should add an asterisk and footnote the report to indicate that data is from foreign participants. If your study includes both domestic and foreign participants, we suggest submitting two separate reports – one for domestic data and one for foreign data, with an asterisk and footnote explaining the foreign data.

NOTE: The enrollment data by race may be lower than the Targeted/Planned enrollment by race because some individuals may designate that they belong to more than one race and will report under "More Than One Race" category. In this case, you may discuss these discrepancies in an attachment to the Inclusion Enrollment report.

Standards for Collecting Data from Study Participants:

When you are planning collection of data on ethnicity and race, as well as sex/gender, you should use the categories listed below in obtaining the data from individuals. The collection of greater detail is encouraged, e.g., on ethnic/racial subpopulations; however, any collection that uses more detail shall be organized in such a way that the additional categories can be aggregated into these minimum categories for reporting data on ethnicity and race. Using self-report or self-identification to collect this information, you should use two separate questions, with ethnicity information collected first followed by the option to select more than one racial designation. When reporting these data in the aggregate, you should report:

(a) the number of subjects in each ethnic category;

(b) the number of subjects who selected only one category for each of the five racial categories;

(c) the total number of subjects who selected multiple racial categories reported as the "number selecting more than one race"; and,

(d) the number of subjects in each racial category who are Hispanic or Latino.

NIH is required to use these definitions 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 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html).

NOTE: The Inclusion Enrollment Report format is not designed for use as a data collection instrument. You should collect the data using instruments prepared for the study and use the information from the study database to fill out the enrollment report. Study participants who select two or more racial categories should be reported in the aggregate in the "More Than One Race" category. An example of a format for collecting information from a study participant can be found in the "Ethnic Origin and Race" section of the Personal Data Form Page (PDF or MS Word) in the PHS 398.

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. NIH is required to use these definitions so that the data collected will allow comparisons to other Federal databases, especially the census and national health

databases. The following definitions 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.

Asian: A person having origins in any if the original peoples of the Far East, Southern 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.

Ethnic/racial subpopulations. In addition to the OMB ethnic and racial categories, NIH uses the following definition for ethnic/racial subpopulations:

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. (http://grants2.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm).

Human Subjects Education Requirement

For grants involving Human Subjects, provide certification for any *new* key personnel or other significant contributors involved in the design or conduct of research involving human subjects that they have completed an educational program in the protection of human subjects.

Vertebrate Animals (Item B)

If there has been no change, check "No Change" on the Progress Report page.

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 for use of vertebrate animals in research and check "Change" on the Progress Report page. Examples of significant changes might include substituting one animal model for another or changing from noninvasive to invasive procedures. If studies involving Vertebrate Animals are planned, and they were not part of the originally proposed research design, then you must comply with the requirements of Section F. "Vertebrate Animals" described in the PHS 398 instructions (MS Word or PDF) and provide the required information to NIH.

e. Publications

Provide **one copy** of each publication not previously submitted to the awarding component. List the complete citation (author(s), title, journal or book, volume, page number, year) of all publications not previously reported. This includes manuscripts submitted or accepted for publication. **Report only those**

publications resulting directly from this grant. State if there have been **no** publications.

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.

7. CHECKLIST

(FORM PAGE 6, MS Word or PDF)

Program Income

See the PHS 398 application instructions (MS Word or PDF) 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 Grant Award will provide specific instructions regarding the use of such income.

Assurances/Certifications

Each progress report to the PHS requires that the following assurances and certifications be verified by the signature of the Official Signing for Applicant Organization on the Face Page of the progress report. Definitions are provided in the Grants Policy Statement and in the PHS 398 application instructions (MS Word or PDF).

If unable to certify compliance where applicable, provide an explanation and place it after the Progress Report (Form Page 5).

Human Subjects
Research Using Human Embryonic Stem Cells
Research on Transplantation of Human Fetal Tissue
Women and Minority Inclusion Policy
Inclusion of Children Policy
Vertebrate Animals
Debarment and Suspension
Drug-Free Workplace
Lobbying
Non-Delinquency on Federal Debt
Research Misconduct
Civil Rights
Handicapped Individuals
Sex Discrimination
Age Discrimination
Recombinant DNA and Human Gene Transfer Research
Financial Conflict of Interest (except Phase I SBIR/STTR)
Prohibited Research
Certification of Research Institution Participation (STTR only)

Facilities and Administrative Costs

Follow the instructions on the Checklist.

8. KEY PERSONNEL REPORT

(FORM PAGE 7, MS Word or PDF)

Using the table, list **all key 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. Include all degrees, role on project, date of birth, annual percent of effort, and the last four digits of the Social Security number. When requesting 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.

Individuals designated at “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 now meet the definition of “key personnel.”

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

III. GENERAL INFORMATION

A. Social Security Number

The PHS requests the last four digits of the Social Security number for accurate identification, referral, and review of progress reports and for management of PHS grant programs. Provision of this section of the Social Security number is voluntary. Please be aware that no individual will be denied any right, benefit, or privilege provided by law because of refusal to disclose this section of the Social Security number. The PHS requests the last four digits of the Social Security numbers under Sections 301 (a) and 487 of the PHS Act as amended (42 USC 241a and 42 USC 288).

B. Government Use of Information Under Privacy Act

The Privacy Act of 1974 (5 USC 552a) is a records management statute and regulates the collection, maintenance, use, and dissemination of personal information by Federal agencies. In accordance with the Act, the PHS is required to provide the following notification to each individual from whom information is requested.

The PHS maintains progress reports and grant records pursuant to its statutory authority for awarding grants. The purpose of the information collection is to aid in the review, award, and administration of PHS programs. Provision of information is voluntary; however, a lack of sufficient information may hinder the PHS' ability to review progress reports, monitor grantee performance, or perform overall management of grant programs.

The Privacy Act authorizes discretionary disclosure of this information within the Department of Health and Human Services (DHHS) and outside the Agency to the public, as required by the Freedom of Information Act and the associated DHHS regulations (45 CFR 5), including: Congress acting within its legislative authority; the National Archives; the General Accounting Office; the Bureau of Census; law enforcement agencies; and pursuant to a court order.

Information may also be disclosed outside the Department for the following purposes:

1. To a Congressional office at the request of the record subject;
2. To the Department of Justice as required for litigation;
3. To the cognizant audit agency for auditing;
4. To qualified experts not within the definition of Department employees, as prescribed in Department Regulations (45 CFR 5b.2), for opinions as part of the progress report review/award process;
5. For an authorized research purpose under specified conditions;
6. To contractors for the purpose of processing, maintaining, and refining records in the system. Contractors will be required to maintain Privacy Act safeguards with respect to such records;
7. To a Federal agency, in response to its request, in connection with the letting of a contract or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the records are relevant and necessary to the requesting agency's decision on the matter; and
8. To the applicant organization in connection with the review of a progress report or performance or administration under the terms and conditions of the award, or in connection with problems that might arise in performance or administration if an award is made.

C. Information Available to the Principal Investigator

Under the provisions of the Privacy Act, principal investigators may request copies of records pertaining to their grant progress reports from the PHS component responsible for funding decisions. Principal investigators 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.

D. Information Available to the General Public

The PHS makes information about awarded grants available to the public, including the title of the project, the grantee institution, principal investigator, 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 **noncompeting supplemental** grant progress reports; pending and funded **noncompeting continuation** progress reports; progress reports of grantees; and final reports of any review or evaluation of grantee 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 grantee 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 deleted and the balance of the document will be released.

ACCESS TO RESEARCH DATA

By regulation (45 CFR 74.36), grantees 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 grantee 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.

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

Research Career Development Award (CDA) Progress Reports

IV. ADDITIONAL INSTRUCTIONS FOR PREPARING CONTINUATION CAREER DEVELOPMENT AWARD (CDA) PROGRESS REPORTS

The instructions in Sections I-III are to be used with these additional instructions to request continuation of all career development awards (K series). For those applying under the Streamlined Noncompeting Award Process (SNAP), use the SNAP instructions in Section II.A, Streamlined Noncompeting Award Process (SNAP) and the instructions below for Items A.4 through A.7. **Supplemental Instructions should be obtained from the awarding component if applicable.**

A. Specific Instructions

1. Detailed Budget for Next Budget Period

(FORM PAGE 2, MS Word or PDF)

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 career mechanism guidelines.

2. Biographical Sketch

(BIOGRAPHICAL SKETCH FORMAT PAGE, MS Word or PDF)

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

3. Other Support

Provide Other Support information for the career award recipient, sponsor/mentor(s), co-sponsors and 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: **MS Word** or **PDF** on the 2590 Forms Page (http://grants.nih.gov/grants/funding/2590/2590.htm#forms).

4. Progress Report Summary

Follow the instructions for regular research projects found in Section II.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 should not exceed two 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, informal instruction in specific research skills, scientific seminars and meetings, training in the responsible conduct of research, visits to other laboratories, etc. Indicate any changes in 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.

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

For the next year of support, provide information on similar activities (to those provided in Item G and Item H for the past year) planned for the next year.

j. Sponsor's Report.

Prepare a concise statement of the awardee's progress and performance, during the past year, 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. The typed name, signature of the sponsor, and date must appear at the end of the Progress Report Summary. For awards without a sponsor/mentor, the person responsible for the candidate's research career development should sign the progress report.

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.

6. CHECKLIST

(FORM PAGE 6, MS Word or PDF)

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

7. KEY PERSONNEL REPORT

(FORM PAGE 7, MS Word or PDF)

Provide the information requested. This is the last page of the progress report. Number all pages consecutively.

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

Institutional Ruth L. Kirschstein National Research Service Award Progress Reports

V. ADDITIONAL INSTRUCTIONS FOR PREPARING A PROGRESS REPORT FOR AN INSTITUTIONAL RUTH L. KIRSCHSTEIN NATIONAL RESEARCH SERVICE AWARD

Progress reports to continue support of a PHS Institutional Ruth L. Kirschstein National Research Service Award (Kirschstein-NRSA) must be submitted on PHS 2590 forms. The due date for these progress reports is determined by the awarding component. Grantees access a website to determine which 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/userreports/pr_due.cfm. Grantees 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 grantee 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.

Additional information on this notification process can be found in the NIH Guide Notice OD-03-054: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-054.html.

This section contains additional instructions, a substitute budget page, and a summary of trainees page to be used to request continuation (noncompeting) support under the PHS Institutional Kirschstein-NRSA Program. Follow both sets of instructions in preparing your progress report.

A. Specific Instructions

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 IACUC review dates. If space is insufficient in Item 7a, indicate "Next Page" and provide the information on a plain sheet of paper after the Face Page.

Check "Yes" and insert "Indefinite" at Item 7a 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.

Item 9. Inventions and Patents

Not applicable.

Item 13. Program Director Assurance

The program director's signature assures that postdoctoral trainees have been informed of payback requirements associated with the Kirschstein-NRSA program.

2. Next Budget Period

(FORM PAGE 2, MS Word or PDF)

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, Fees, and Health Insurance

Itemize tuition, individual fees, and either self-only or family medical insurance. If tuition varies (e.g., in-state, out-of-state, or student status), identify these separately. Tuition at the postdoctoral level is limited to that required for specified courses. Tuition, fees, and medical insurance may be requested only to the extent that the same resident or nonresident tuition, fees, and medical insurance are charged to typical non-Federally-supported students.

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

Funds to defray other costs of training, such as 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. No further itemization or explanation is required.

3. BUDGET JUSTIFICATION

(FORM PAGE 3, MS Word or PDF)

Indicate whether all stipends awarded for the current budget period will be used and explain any estimated unexpended balance.

4. BIOGRAPHICAL SKETCH

(BIOGRAPHICAL SKETCH FORMAT PAGE, MS Word or PDF)

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

5. OTHER SUPPORT

Not applicable.

6. PROGRESS REPORT SUMMARY

(FORM PAGE 5, MS Word or PDF)

Use the following instructions to prepare a progress report, which provides a brief presentation of the accomplishments and changes in the training program during the reporting period, following the outline below:

a. Training Program

1. Provide a brief 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, significant new training content, procedures or experiences, and indicate how these aid in strengthening and realizing the objectives and goals of the program.
2. Describe the nature of the instruction in the responsible conduct of science and the extent of trainee and faculty participation.
3. Describe activities related to recruitment of trainees from underrepresented racial and ethnic groups.

b. Study Subjects

Provide data on the Inclusion Enrollment Report (MS Word or PDF) 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. Use Kirschstein-NRSA Summary of Trainees Additional Form Page 5 (MS Word or PDF) to provide the following information. 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, and research involvement of the position, and any other relevant information.
2. Summarize information on the gender and racial/ethnic distribution of the trainees supported on this grant during the reporting period. Use the table on the "Inclusion Enrollment Report Format Page." Indicate the name of the training program as the "Study Title" and the total number of trainees supported during the reporting period as the "Total Enrollment." Leave the section "Protocol Number" blank. In Part A of the table, indicate for all trainees the numbers that fall into each ethnic and racial category. The number of multi-racial trainees will be in entered into the row "more than one race." Normally, the unknown or not-reported categories will not be needed. In Part B of the table, indicate for "Hispanic or Latino" trainees the numbers that fall into each racial category. Definitions of the indicated racial and ethnic categories are described in the PHS 398 instructions.

3. Include a brief paragraph that describes the research project and course work of current trainees. Provide the name of the faculty supervisor.
4. List the titles and complete references (author(s), journal or book, year, page number) of all trainee publications not previously reported. This includes manuscripts submitted or accepted for publication.

7. CHECKLIST

(FORM PAGE 6, MS Word or PDF)

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 allowable direct costs (exclusive of tuition and related fees). 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. State and local government agencies will receive awards at their full Facilities and Administrative cost rate.

8. KEY PERSONNEL REPORT

(FORM PAGE 7, MS Word or PDF)

Not applicable.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

SMALL BUSINESS INNOVATION RESEARCH (SBIR) AND SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) AWARDS

Progress Reports

VI. ADDITIONAL INSTRUCTIONS FOR PREPARING A PROGRESS REPORT FOR AN SBIR AND STTR AWARD

Progress reports to continue support of a PHS Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) Award must be submitted on PHS 2590 forms. The due date for these progress reports is determined by the awarding component. Grantees access a website to determine which 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/userreports/pr_due.cfm. Grantees 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 grantee 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.

Additional information on this notification process can be found in the NIH Guide Notice OD-03-054: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-054.html.

Follow the instructions in Sections I and II of this document. This section contains additional instructions pertinent to Fast Track SBIR and STTR awards.

Fast-Track SBIR/STTR Awards

A Fast-Track Phase II application may be funded following submission of an original PHS 2590 Non-competing Grant Progress Report (plus two copies). Follow the simplified instructions under the Streamlined Noncompeting Award Process (SNAP) found in Section II.A for all portions except the research plan, which should include the following:

1. A Phase I Final Progress Report: Follow the application instructions in the NIH SBIR/STTR Phase II Solicitation: Section 8. Research Plan, Item c. Preliminary Studies/Phase I Final Report at http://grants1.nih.gov/grants/funding/sbirsttr2/PhaseII_SBIRSTTR.pdf or http://grants.nih.gov/grants/funding/sbirsttr2/PhaseII_SBIRSTTR.doc.

2. 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 grantee; and (2) describing the progress achieved relative to the milestones.

3. A one-page abstract describing the research plan for Phase II. (See Section 6. D, "Plans" of the Progress Report Summary). 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.

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

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 Grant Progress Report is due two months prior to the anticipated start of Phase II and should be sent to the address noted on the Notice of Grant Award.

The appropriate grants management and program staff of the awarding component will review the Phase I Grant Progress Report. If the continuation request is not approved, then written notification will be sent to the applicant.

Final Report Requirements

PHASE II FINAL PROGRESS REPORT

A Phase II Final Progress Report is required to close out your Phase II grant.

You must submit a Final Report within 90 days of the project period end date. Submit the **original and one copy** of the report to the **Grants Management Office** of the awarding component (IC) within **90 days** of the termination of the grant.

Final reports serve as an important source of material for staff of the awarding component in preparing annual reports, for planning purposes, and in communicating scientific accomplishments achieved through the SBIR/STTR program.

There is no “form page” for a Final Report. It may be typed on plain white paper (or you may use the PHS 2590 Continuation Page). *The recommended length for the narrative portion is 10 pages*.

The format for the Phase II Final Progress Report is as follows:

1. State the beginning and end dates for the period covered by the SBIR/STTR **Phase II** grant.

2. List all key personnel who worked on the project during that period (include titles, dates of service, and number of hours devoted to the project).

3. Summarize the specific aims of the Phase II grant.

4. Provide a succinct account of published and unpublished results, indicating progress toward achievement of the originally stated aims. Include the Inclusion Enrollment Report (MS Word or PDF) with the final enrollment data for clinical research.

5. List titles and complete references to publications, and manuscripts accepted for publication, if any, that resulted from the Phase II.

6. List patents, copyrights, trademarks, invention reports and other printed materials, if any, that resulted from the Phase II or describe patent status, trade secrets or other demonstration of IP protection.

7. Describe of the technology developed from this SBIR/STTR, its intended use and who will use it.

8. Describe the current status of the product (e.g., under development, commercialized, in use, discontinued).

9. If applicable, describe the status of FDA approval for your product, process, or service (e.g., continuing pre-IND studies, filed an IND, in Phase I (or II or III) clinical trials, applied for approval, review ongoing, approved, not approved, not ready to submit for FDA approval).

10. Describe how your company has benefited from the program and/or the technology developed (e.g., firm's growth, follow-on funding, increased technical expertise, licensing agreements, spin-off companies, public offering [include stock exchange and symbol]).

11. List of the generic and/or commercial name of product, process, or service, if any, that resulted from SBIR/STTR funding. If applicable, indicate the number of products sold.

12. Provide the current number of employees (total full time equivalents [FTEs]).