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

## Non-Competing Continuation Progress Report (PHS 2590)

Instructions for PHS 2590
Revised xx/2009

Forms Approved Through xx/xx/20xx
OMB No. 0925-0001

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# Notable Changes

Changes to the Instructions since 11/2007:

- All Personnel Report (2.2.8) – Instruction updated to “List all personnel for the current budget period who participated on the project for one person month per year or more.” This update addresses a longstanding analytical need required by the PHS Act of 1974. Also, note it is now required that all individuals with a postdoctoral role with one person month or more of measurable effort on the project, must complete a **one-time** registration in the eRA Commons.

- Revised NIH Public Access Policy implemented. See the 01/11/2008 NIH Guide Notice and NOT-OD-08-119 for additional information. Clarification of use of Data Tables 12A and 12B for the Non-competing NRSA's. (04/14/2008)

Implementation of NIH Reform Act of 2006 (P.L/ 109-482)

- Table 12A, required for institutional research training applications, is modified to collect data on percentage of students who successfully attain a doctoral degree and average time to receive a doctoral degree.

- A new Graduate Student Assurance, that this same information is provided to students applying to graduate programs, is required as applicable.

- Progress Report Summary (2.2.6 B) As part of the Enhancing Peer Review Initiative, PD/PIs are asked, if applicable, to address any changes to the innovative potential of the project.

**Changes to specific form and format pages:**

All Personnel Report Page – Revised to collect information on all personnel, added column to collect the eRA Commons user ID, and month and year of birth.

# 1. Continuation Progress Report

Progress reports are required to continue support of a PHS grant and for NIH grantees. In general annual progress reports for the NIH must be **submitted two months** before the beginning date of the next budget period using the PHS 2590. The PHS 2590 can be used for more frequent reporting requirements such as interim reporting, and/or final reporting. All annual NIH progress reports must 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

For more information on the PHS 2590, contact Grants Information at GrantsInfo@nih.gov or call 301-435-0714.

## 1.1 Continuation Progress Reports for Other PHS Agencies

While other PHS awarding agencies use these same application forms, some may have application requirements that are different from those for NIH grantees. 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.

Further, as you will see references to the NIH Grants Policy Statement (NIHGPS) throughout these instructions, please note that the NIHGPS is not applicable to the other PHS awarding agencies. The agencies listed below follow the Health and Human Services Grants Policy Statement (HHSGPS) as their awarding guidance (http://www.hhs.gov/grantsnet/).

| | |
|---|---|
| **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

NIH grantees are required to submit the completed, signed original progress report (with required signature). NIH 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. NIH 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 PD/PI.

Progress report due dates are also available in the Commons Status system. Commons registered institutions and PD/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 instructions for preparing continuation progress reports for Career Development Awards are found in Section 5 and additional instructions for preparing progress reports for Institutional Research Training Awards are found in Section 6.

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. Investigators are encouraged to retain these instructions for future submissions.

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, staying within the margin limitations indicated on the form. 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.

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

## 1.3 Electronic Submission of SNAP Progress Reports (eSNAP)

Reminder: Review and update your eRA Commons Personal Profile as necessary.

NIH Grantee Institutions have the ability to electronically submit SNAP progress reports for most awards. 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.

If you are using the NIH eSNAP to electronically prepare and submit your non-competing (T-5) SNAP progress report, do not use the PHS 2590 fillable form pages for any file uploads. Text inserted into the fillable form pages is not saved once the progress report is submitted to NIH. Guidance on eSNAP submission is documented in the eSNAP User Guide found at: http://era.nih.gov/commons/index.cfm. Questions on eSNAP submission should be directed to:

> Email the Commons Help Desk at commons@od.nih.gov.
>
> Call the Commons Help Desk at 1-800-504-9552 (toll-free) or 301-402-7469; 301-451-5939 (TTY). Business hours are M-F 7am-8pm Eastern Time.

AHRQ, CDC, FDA and IHS do not participate in the eSNAP process.

## 1.4 GrantsInfo, DEOIR, OER, National Institutes of Health

The Division of Extramural Outreach and Information Resources (DEOIR) provides 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.

## 1.5 Paperwork Burden

PHS estimates that it will take approximately 15 hours to complete this progress report. 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.

## 1.6 Registration Reminders

### 1.6.1 DUNS Registration for the 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 authorized organizational official and used consistently for all submissions. The authorized organizational representative 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 Financial Assistance 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 additional subaward/consortium organization must also be provided.

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

A DUNS number is required for Central Contractor Registration (see 1.6.2 below).

### 1.6.2 CCR Registration for the Organization

Prior to submission of all progress reports-paper and electronic-organizations are required to be registered in the Central Contractor Registration (CCR). Organizations must maintain the currency of

the information in the registry and renew the registration annually. A DUNS number is required for CCR registration.

CCR 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 CCR 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 Financial Assistance Transparency Act (FFATA) of 2006* (P.L. 109-282).

Organizational information entered into the CCR 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 authorized organizational representative should be consulted to determine if the organization has properly completed and maintained CCR registration. Additional information on CCR registration is found at: http://www.ccr.gov/.

# 2. Preparing Progress Reports

For submission of SNAP progress reports, follow the instructions under Section 2.1 below.

For submission of non-SNAP progress reports, follow the instructions under Section 2.2.2, Detailed Budget for Next Budget Period. These instructions are applicable to grantees of AHRQ, CDC, FDA and IHS which do not participate in the SNAP process.

## 2.1 NIH 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 2.2). When additional information is required, use the appropriate form page. For example, the biographical sketch page is still required for new senior/key personnel and/or new other significant contributors.

These simplified instructions apply to all R series grant activity codes 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 and Phase II SBIR/STTR, grantees should review the Notice of Award to determine if their project is subject to or excluded from the SNAP provisions. Career award activity codes (Ks) are also routinely covered under SNAP. Those activity codes routinely excluded from SNAP are generally those that do not have the authority to automatically carry over unobligated balances (centers, cooperative agreements, institutional training including Kirschstein-NRSA grants, non-Fast Track Phase I SBIR and STTR awards), clinical trials (regardless of activity codes), Program Project Grants (P01s) and Outstanding Investigator Grants (R35s). All NIH award notices identify whether the grant is subject to or excluded from SNAP.

### 2.1.1 SNAP Instructions for Submitting the Progress Report

Complete Face Page (Form Page 1) except for items 8a and 8b, the Progress Report Summary (Form Page 5), and the Senior/Key Personnel Report (Form Page 7). Complete the Checklist Page (Form Page 6) only if there is a change in Project/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 5, which includes Items 5.1.4 through 5.1.7.**

## 2.1.2 SNAP Questions

**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 senior/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 (http://grants.nih.gov/grants/funding/phs398/phs398.html). 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 PD/PI and for those individuals considered by the PD/PI to be key to the project. Senior/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 “senior/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 PD/PI(s) 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 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. 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 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 approved 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. 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.

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 Award.**

## 2.2 Specific Instructions

### 2.2.1 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 at http://grants.nih.gov/grants/funding/2590/2590.htm.**

**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 PI Leadership Plan. Remember, all designated contact PD/PIs must be from the applicant institution if PD/PIs are from more than one Institution.

#### 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.

#### 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 (http://grants.nih.gov/grants/funding/phs398/phs398.html). Guidance pertaining to Human Subjects Research, including clinical trials and NIH-Defined Phase III Clinical Trials, may be found in Part II of the PHS 398 application instructions. Human subject definitions are found in Part III of the PHS 398. 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 if the research is exempt from HHS regulatory requirements for the protection of human subjects (http://grants.nih.gov/grants/funding/phs398/phs398.doc#Human_Subjects_Exemption_Cat).

**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 PHS 398 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 PHS 398 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 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. 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 PHS 398 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 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/or certifications be verified by the signature of the Official Signing For Applicant Organization on the Face Page of the application. These assurances are explained in Part III: Policies, Assurances, Definitions, and Other Information of the PHS 398 application instructions. Applicants and grantees must comply with a number of additional public policy requirements. Refer to your institution's research grant administrative office or the *NIH Grants Policy Statement* (http://grants.nih.gov/grants/policy/policy.htm) for additional information.

The policies, assurances and certifications listed below may or may not be applicable to your project, program, or type of applicant organization.

- Human Subjects Research
- Research on Transplantation of Human Fetal Tissue
- Research Using Human Embryonic Stem Cells
- Women and Minority Inclusion Policy
- Inclusion of Children Policy
- ClinicalTrials.gov Requirements
- 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 Research, including Human Gene Transfer Research
Financial Conflict of Interest (except Phase I SBIR/STTR)
Smoke-Free Workplace
Prohibited Research
Select Agent Research
Project Director/Principal Investigator Assurance
Impact of Grant Activities on the Environment and Historic Properties
Institutions Receiving Awards for Training of Graduate Students for Doctoral Degrees

### 2.2.2 Detailed Budget for Next Budget Period

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 2.2.3 - 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**. Grantees 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 PHS 398 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.

## 2.2.3 Budget Justification

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.

## 2.2.4 Biographical Sketch

BIOGRAPHICAL SKETCH FORMAT PAGE

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

Senior/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 senior/key personnel. Consultants and those with a postdoctoral role should also be included if they meet the same definition. Individuals providing technical services are not considered senior/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.

Complete the education/training block at the top of the format page. Begin by listing your baccalaureate or other initial professional education, such as nursing. Include your postdoctoral training and residency training as applicable, and complete sections A, B, C, and D below:

A. Personal statement. Briefly describe why your experience and qualifications make you particularly well-suited for your role (e.g., PD/PI, mentor, participating faculty) in the project that is the subject of the application.

B. Positions and Honors. List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

C. List up to 15 selected peer-reviewed publications or manuscripts in press (in chronological order). Do not include manuscripts submitted or in preparation. Publications should be divided into the following groups: 5 most recent publications, 5 best publications, and 5 publications most relevant to the application. Publications may appear in more than one category. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm. Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PMCID numbers along with the full reference (note that copies of publicly available publications are not accepted as appendix material.)

D. Research Support. List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). *Begin with the projects that are most relevant to the research proposed in the application.* Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.

## 2.2.5 Other Support

For the purposes of the continuation progress report, other support information is **only** required on **active** support for all senior/key personnel. Refer to the PHS 398 application instructions 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 senior/key personnel.

## 2.2.6 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," **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 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 your 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. 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)**

**When submitting a non-competing progress report that includes applicable trial/s:** NCT number/s, Brief Title/s (as defined by ClinicalTrials.gov, see http://prsinfo.clinicaltrials.gov), and the identity of the responsible party (or parties) are to be included in the Human Subjects section of the progress report (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-023.html).

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 Protection of Human Subjects section as described in the PHS 398 Research Plan instructions. Follow the instructions for Preparing the Section on Protection of Human Subjects in Part II.3. Include designated headings as appropriate for Exempt Human Subjects Research, Non Exempt Human

Subjects Research, Clinical Trial, or NIH Defined Phase III Clinical Trial. Include, as appropriate, sections on Data and Safety Monitoring (Part II.4.1.5), Inclusion of Women and Minorities (Part II.4.2), and Inclusion of Children (Part II.4.4). 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 a Protection of the Human Subjects section as instructed in Part II of the PHS 398 instructions.

If studies involving human subjects are planned, and they were not part of the originally proposed research design, then you must provide a Protection of Human Subjects section as instructed in Part II of the PHS 398 instructions, and provide the information required in Item 4 of the Face Page of the PHS 398 grant application (see instructions in Part I of the PHS 398 instructions).

Note that Public Law 110-85, enacted 09/27/2007, mandates registration and results reporting of applicable clinical trials in ClinicalTrials.gov (see Part II, 4.1.6 and Part III, 2.1.6 of the PHS 398 and Guide Notice at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-023.html). In signing the application Face Page, the authorized organizational representative of the applicant 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 (see Section 4.6 of 2590 and Part III, Section 2.1.6 of the PHS 398).

**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 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 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 (http://grants.nih.gov/grants/funding/phs398/Inclusion498version.doc) or the Inclusion Enrollment Report. 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 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.

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 Table *and* an Inclusion Enrollment Report describing data collected to-date. Explain the changes in a footnote or attachment to the report. The NIH Policy on Reporting Race and Ethnicity Data for Subjects in Clinical Research is described and referenced in Part II, Section 5.8 of the PHS 398.

**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 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. Refer to the definition of "NIH-Defined Phase III Clinical Trial" in Part III.3, of the PHS 398 under Human Subjects Research Definitions and Terms.

**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.

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).

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 in the PHS 398 (http://grants.nih.gov/grants/funding/phs398/phs398.html).

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 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://grants.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* senior/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. This requirement may not

apply to other awarding agencies. Non-NIH grantees should contact their awarding agency for guidance (refer to table in Section 1.1).

**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 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, then you must comply with the requirements of Item 5.5.10, “Vertebrate Animals,” described in the PHS 398 instructions, and provide the required information to NIH. Before activities with live vertebrate animals begin, the applicant must provide all information required in Item 5.5.10 of the Research Plan with certification of current IACUC approval.

**Select Agent Research (Item C)**

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

Check "Change" on the Progress Report Summary page if proposed research involving Select Agents is different from that proposed in the previous submission. Include an explanation of how research plans differ and provide a new or revised "Section 5.5 Select Agent Research" from the PHS 398 instructions reflecting these changes.

If Select Agent Research planned for the coming year was described in the Research Plan of the PHS 398 application, but had not been approved by regulatory authorities, provide the Select Agent Research information requested in the PHS 398 instructions.

If studies involving Select Agents are planned, but were not part of the originally proposed research design, then you must provide a section on Select Agents as instructed by the PHS 398 Research Plan Instructions in Part I.5.5 and provide the information required in Item 5.5.11.

**Multiple PD/PI Leadership Plan (Item D)**

This section is only applicable if Multiple PD/PIs are part of the NIH approved project. Check "No Change" on the Progress Report Summary page (Form Page 5) if there is no change in the leadership plan as originally proposed and approved.

Check "Change" on the Progress Report Summary page if there has been any change in the governance and/or organizational structure of the Multiple PD/PI Leadership Plan including communication plans and procedures for resolving conflicts. Also discuss 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, check “Change” on the Progress Report Summary page and address this change and the impact, if any, the change has on the administrative, technical, and scientific responsibilities for the PD/PIs.

### E. Publications

Report publications resulting directly from this grant that you have not previously reported, including manuscripts submitted or accepted for publication. Provide the complete citation (author(s), title, journal or book, volume, page number, year). If available electronically provide a url or PMCID number. If not available electronically you may provide one copy with the progress report. State if there have been no publications.

For each publication that falls under the Public Access Policy, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567), at the end of the citation. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm.

For additional information on compliance with the Public Access Policy see NIH Guide Notice NOT-OD-08-119.

### 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 NOTICE OD-08-023, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-023.html and NOTICE OD-07-088, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html).

## 2.2.7 Checklist

FORM PAGE 6

### Program Income

See the PHS 398 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.

### Assurances/Certifications

Each progress report to the PHS requires that the policies, assurances and certifications listed in Section 2.2.1 be verified by the signature of the Official Signing for Applicant Organization on the Face Page of the progress report (see Item 13). If unable to certify compliance where applicable, provide an explanation and place it after the Progress Report (Form Page 5).

**Facilities and Administrative Costs**

Follow the instructions on the Checklist.

### 2.2.8 All Personnel Report

FORM PAGE 7

List **all 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. 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. The Commons ID is required for all PD/PIs and all individuals with a postdoctoral role; it is optional for all other personnel.

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 and meet the definition of “senior/key personnel.”

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

## 3. Final Progress Report

A final progress report is required for any grant that is terminated and any award that will not be extended through award of a new competitive segment. The final progress report should include a summary of progress toward the achievement of the originally stated aims, a list of significant results (positive or negative), and a list of publications. When citing articles that fall under the Public Access Policy, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm.

The final progress report also should address the following:

- Report on the inclusion of gender and minority study subjects (using the gender and minority inclusion table as provided in the PHS 2590)

- Where appropriate, indicate whether children were involved in the study or how the study was relevant for conditions affecting children (see "Public Policy Requirements and Objectives—Requirements for Inclusiveness in Research Design—Inclusion of Children as Subjects in Clinical Research" and the PHS 398)

- Describe any data, research materials (such as cell lines, DNA probes, animal models, etc.), protocols, software, or other information resulting from the research that is available to be shared with other investigators and how it may be accessed.

If there are any other specific requirements set forth in the terms and conditions of the award they must be addressed in the final progress report as well. Additional information on submitting final progress reports to AHRQ, CDC, FDA and IHS can be obtained from their website.

**ELECTRONIC SUBMISSION OF FINAL PROGRESS REPORT**

Electronic submission is strongly encouraged for all NIH grantees. Grantee institutions registered in the eRA Commons should submit the final progress report electronically through the eRA Commons available at https://commons.era.nih.gov/commons/. Additional information on electronic submission of closeout documents is available at the NIH eRA Commons homepage or by contacting the eRA help desk at: http://ithelpdesk.nih.gov/eRA/ or Toll-free (866) 504-9552, Phone 301-402-7469, TTY 301-451-5939.

If closeout documents are not submitted electronically through the eRA Commons, the original final progress report should be submitted to the centralized mailing address in Section 1.

Additional information on submitting closeout documents to AHRQ, CDC, FDA and IHS can be obtained from their website.

# 4. General Information

## 4.1 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 postdoctoral individuals supported on 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 and those with a postdoctoral role 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 confidential, 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. 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. Declining to provide information does not affect consideration of an application; however, for some programs (e.g., Ruth L. Kirschstein National Research Service Awards and Research Career Development Awards) citizenship data is required to determine eligibility.

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).

## 4.2 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.

## 4.3 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.

## 4.4 Information Available to the General Public

The PHS makes information about awarded grants available to the public, including the title of the project, the grantee 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 (formerly noncompeting supplements)** progress reports; pending and funded **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 redacted and the balance of the document will be released.

## 4.5 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.

## 4.6 ClinicalTrials.gov Requirement

Public Law 110-85 mandates registration and results reporting of "applicable clinical trials" in ClinicalTrials.gov. Under the statute, these trials generally include: (1) Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation; and (2) Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric postmarket surveillance. Review the statutory definition of applicable clinical trial to identify if registration is required to comply with the law (See PL 110-85, Section 801(a), (adding new 42 U.S.C. 282(j)(1)(A)): http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf).

NIH encourages registration of ALL trials whether required under the law or not.

Registration is accomplished at the ClinicalTrials.gov Protocol Registration System Information Website (http://prsinfo.clinicaltrials.gov/). A unique identifier, called an NCT number will be generated during the registration process.

For new and renewal (competing) applications that include ongoing clinical, trials provide the NCT number/s, Brief Title/s (as defined by ClinicalTrials.gov, see http://prsinfo.clinicaltrials.gov/s801-new-requirements.pdf), and the identity of the responsible party (or parties) in the human subjects section of the Research Plan under a section heading entitled ClinicalTrials.gov. The entity responsible for registering is the “responsible party.” The statute defined the responsible party as:

(1) the sponsor of the clinical trial (as defined in 21 C.F.R. 50.3) (http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2003/aprqtr/pdf/21cfr50.3.pdf), or

(2) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee (provided that “the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements” for submitting information under the law) (http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf). See PL 110-85, Section 801(a), (adding new 42 U.S.C. 282(j)(1)(A)(ix)).

If a new applicable clinical trial is proposed, under the heading ClinicalTrials.gov include a statement that the application includes a trial which requires registration in ClinicalTrials.gov. The signature on the application of the Authorized Organizational Representative assures compliance for the registration of any such trial.

For additional information and guidance see NIH Guide Notices at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-014.html and http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-023.html.

In addition to the requirements for the registration of clinical trials, an expanded ClinicalTrials.gov database will accept "basic results" summary data necessary to satisfy statutory requirements. Results of clinical trials of FDA-approved drugs, biologics, and devices must be reported on ClinicalTrials.gov within 12 months of the estimated or actual completion date of the trial, whichever date is earlier. Submission will be publicly posted on ClinicalTrials.gov.

# 5. Additional Instructions for Preparing Continuation Career Development Award (CDA) Progress Reports

The instructions in Sections 1-3 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 2.1, Streamlined Noncompeting Award Process (SNAP) and the instructions below for Items 5.1.4 through 5.1.7. **Awardees should consult the applicable Funding Opportunity Announcement and the awarding Federal agency for any supplemental Instructions.**

## 5.1 Specific Instructions

### 5.1.1 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.

### 5.1.2 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.

### 5.1.3 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).

### 5.1.4 Progress Report Summary

Follow the instructions for regular research projects found in Section 2.2.6, 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. 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.

## 5.1.5 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.

## 5.1.6 Checklist

FORM PAGE 6

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

### 5.1.7 All Personnel Report

FORM PAGE 7

Provide the information requested for the awardee and sponsor(s), if applicable. This is the last page of the progress report. Number all pages consecutively.

# 6. Additional Instructions for Preparing a Progress Report for an Institutional Research Training Grant, Including Ruth L. Kirschstein National Research Service Awards

Progress reports to continue support of a PHS Institutional Ruth L. Kirschstein National Research Service Award (Kirschstein-NRSA) or non-NRSA research training grant 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 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/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.

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 your progress report.

## 6.1 Specific Instructions

### 6.1.1 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.

## 6.1.2 Next Budget Period

FORM PAGE 2

A new policy concerning tuition, fees and health insurance for Kirschstein-NRSA training grants was issued in the NIH Guide August 18, 2006; see NOT-OD-06-093 for more details. Two sets of instructions are now provided in this section to provide separate guidance for awards issued under the old and new tuition policies. **For non-NRSA training grant programs, refer to the FOA for instructions about budget reporting.**

#### 2a. Sunsetting Policy

These instructions apply to non-competing continuation progress reports where the last competing award was issued prior to fiscal year 2006 (October 1, 2005 through September 30, 2006). These grants have health insurance awarded as part of the tuition and fees budget category and will continue this business practice until the next competitive renewal application.

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 level 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 health insurance. 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, fees, and health insurance may be requested only to the extent that the same resident or nonresident tuition, fees, and health 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.

**2b. Transitioning Pilot Policy**

These instructions apply to non-competing continuation progress reports where the last competing award was issued in fiscal year 2006 and beyond. (Note the Federal fiscal year is from October through September.) These grants have health insurance awarded as part of the training related expenses budget category.

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 new policy for funding of tuition, fees, and health insurance, NOT-OD-06-093, dated August 18, 2006.

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.

## 6.1.3 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.

## 6.1.4 Biographical Sketch

BIOGRAPHICAL SKETCH FORMAT PAGE

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

## 6.1.5 Other Support

Not applicable.

## 6.1.6 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 grantees 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, the role of external advisory committees, 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 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 of Select Agent Research described in Section 2.2.6.D.

## B. Study Subjects

Provide data on the Inclusion Enrollment Report 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 12A and/or 12B, 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.

   Grantees that have never completed Table 12A and/or Table 12B should provide the applicable Table(s) with complete data on all trainees supported by the grant. Instructions for completing Tables 12A and 12B may be found in the PHS 398 Instructions for Data Tables (see: http://grants.nih.gov/grants/funding/phs398/phs398.html#DataTableInstruct). Thereafter, updated tables will be required with each progress report through the end of the project period.
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 all 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 PHS 398 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. Citations that are not covered by the 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.

   Peer-reviewed trainee publications that arise from support of the training grant must be submitted to PubMed Central in accord with the Public Access Policy, and the PubMed Central reference number (PMCID) or NIH Manuscript Submission reference number (NIHMS ID) provided. If the publication was already submitted because it also arose as the result of other NIH support, simply provide the PMCID or NIHMS ID. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm.

## 6.1.7 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.

## 6.1.8 All Personnel Report

FORM PAGE 7

Not applicable.

# 7. 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 PD/PIs registered in the eRA Commons, the progress report due information is available in the Commons Status system. Commons-registered institutions and PD/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 Continuation Progress Report. Follow the simplified instructions under the Streamlined Noncompeting Award Process (SNAP) found in Section 2.1 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 Grants.gov SBIR/STTR Application Guide SF424 (R&R), Section 5.4, Research Plan Component, Item 4, Preliminary Studies/Progress Report at http://grants.nih.gov/grants/funding/424/index.htm.
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 2.2.6. 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 Continuation 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 Award.**

The appropriate grants management and program staff of the awarding component will review the Phase I Continuation 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** report to the Central mailing address listed in Section 1 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 senior/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 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.

   When citing articles that fall under the Public Access Policy, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm.
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]).