

NIH Announces Interim Changes to the PHS398 Application and Instructions

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Key Dates

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The PHS398 has been revised to incorporate a number of business process changes that have been implemented since the publication of the 9/2004 revision. This Guide Notice describes the particular business process change and the corresponding changes to the PHS398 application forms and instructions. Applicants should also review several other companion announcements:

- [NOT-OD-06-054](#): *NIH Announces Change in Business Process: Replacing the Principal Investigator Signature on Grant Applications, Progress Reports, and Prior Approval Requests with an Institutional Compliance Requirement*
- [NOT-OD-06-055](#): *NIH/AHRQ Announce Change in Business Process Concerning eRA Commons Verification of Electronically Submitted Applications*
- [NOT-OD-06-057](#): *NIH Announces Changes to the SF424 (R&R) Instructions*
- [NOT-OD-06-058](#): *NIH Announces Interim Changes to the PHS2590 Noncompeting Progress Report Forms and Instructions.*

Revised forms (dated rev. 4/06) and instructions are available for immediate use and are **required** for paper applications being prepared for submission/receipt dates on/after May 10, 2006 . After this date, applications submitted using previous versions of form pages that have been updated, may be delayed in the review process.

- Applicants Preparing Applications for Submission/receipt Dates Prior to May 10, 2006 : During the transition, form pages for both PHS398 (Revised 9/2004) and PHS398 (Interim Revision 4/2006) will be posted at: <http://grants.nih.gov/grants/funding/phs398/phs398.html>. Use only form pages with the (Rev. 9/04) date. While you will continue to use the 9/2004 version of the Instructions, do not use any of the form-page hyperlinks within those instructions; they will misdirect you to the new forms.

- Applicants Preparing Applications for Submission/receipt Dates On/After May 10, 2006 : During the transition, form pages for both PHS398 (Revised 9/2004) and PHS398 (Interim Revision 4/2006) will be posted at: <http://grants.nih.gov/grants/funding/phs398/phs398.html>. Use only form pages with the (Rev. 4/06) date. Use the Instructions labeled "Interim Revision 4/2006", which include hyperlinks to the appropriate new forms.

Change in Business Process: Replacing PI Signature on the Application with an Institutional Compliance Requirement

A new business practice is being implemented by replacing the signature of the Principal Investigator (PI) as a part of competing applications with an institutional compliance requirement where applicant organizations will capture and retain the PI signature as part of their institutional review/approval process.

Effective with PHS398 applications prepared for submission/receipt dates on/after May 10, 2006 , the signature of the Principal Investigator is no longer required as a part of a submitted application. Instead, a new compliance requirement is now implemented whereby the applicant organization agrees to secure and retain at the organization a written assurance from the Principal Investigator (PI) prior to submitting an application to the PHS. While this assurance is no longer required as part of the submitted application, it remains a compliance requirement. Therefore, organizations must retain a unique signature and date for each submitted application. This assurance must be available to the sponsoring agency or other authorized HHS or Federal officials upon request. Such an assurance must include at least the following certifications: (1) that the information submitted within the application is true, complete and accurate to the best of the PI's knowledge; (2) that any false, fictitious, or fraudulent statements or claims may subject the PI to criminal, civil, or administrative penalties; and (3) that the PI agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application. When multiple PIs are proposed in an application, this assurance must be retained for all named PIs.

Specific Changes include:

- Face Page (Form Page 1): Has been revised to remove the PI signature item. Corresponding instructions have also been deleted.
- Checklist Form Page: Section II. Assurances has been revised to include the PI Assurance.
- Part III Policy/Assurances/Definitions: Section II/Assurances has been revised to include the PI Assurance as an institutional compliance requirement.

See NIH Guide Notice [NOT-OD-06-054](#) for additional information on this particular business process change.

Change in Business Process: Measuring Effort Devoted to Projects

Transitioning to the SF424 Research and Related (R&R) has introduced a new business practice for measuring effort devoted to a project—person months (see [Usage of Person Months](#) Frequently Asked Questions and [Percent Effort to Person Months Calculator](#) Excel spreadsheet). Personnel working on projects now indicate effort by indicating the number of calendar, academic, and/or summer months. To keep a consistent business practice in place for all applications, regardless of which set of forms is being used, the PHS398 has also been revised to reflect this new effort measure. Specific changes include:

- **Form Page 4 (Detailed Budget Page):** The Personnel section of the budget has been revised to replace Type of Appointment and Percent Effort, with the 3 columns of person months—calendar, academic, and summer.
- **Key Personnel Format Report:** This format page has been revised to replace the Percent Effort column with the 3 columns of person months—calendar, academic, and summer.
- **Modular Instructions, Budget Justification:** The Personnel Budget Justification instructions have been revised to reflect person months (calendar, academic, and summer) as the measure for effort.
- **Other Support Instructions:** The Other Support instructions have been revised to reflect person months (calendar, academic, and summer) as the measure for effort. Note, Other Support information continues to be required as a Just-In-Time submission.
- **General Instructions Changes:** Changes have been made throughout the instructions to include appropriate guidance for measuring effort in terms of person months.

Change in Business Process: Including Publications as Appendix Material

As described in NIH Guide Notice [NOT-OD-06-051](#) and clarified in Notice [NOT-OD-06-053](#), effective for applications for submission/receipt dates of May 10, 2006 and beyond, the instructions for including paper publications as appendix material has changed. The new process is:

- **Publications in press :** Include only a publication list with a link to the publicly available on-line journal article or the NIH PubMed Central (PMC) submission identification number. Do not include the entire article.

- **Manuscripts accepted for publication but not yet published** : The entire article should be submitted and may be stapled.
- **Manuscripts published but an online journal link is not available** : The entire article should be submitted and may be stapled.

Implementing Multiple Principal Investigators (PIs)

[NIH Guide Notice OD-06-036](#) released February 7, 2006 announced NIH's preliminary plans to incorporate multiple PIs into the application business process. The PHS398 has now been modified to accommodate multiple PIs in competing applications.

Applicants are reminded that this initiative is still in a pilot phase. Only applications in response to specific funding opportunity announcements that included multiple PIs as an option should be following these new instructions at this time.

Changes to specific Form Pages and corresponding instructions include:

- **Face Page (Form Page 1)** : This page has been revised to include a Form Page 1 (continued). Form Page 1 (continued) accommodates the collection of the PI information (section 3 of the Face Page) for all individuals designated as PI by the applicant organization. Form Page 1 (continued) is only required when Multiple PIs are being proposed. All applications proposing a single PI will use only Form Page 1.
- **Face Page Item 3h. eRA Commons User Name** : This is now a required field for all PIs, even those applications proposing only a single PI. Since the mailing of paper review outcome notifications and summary statements has been eliminated (See [NOT-OD-05-075](#)), the eRA Commons is now the tool for PIs to access this information. Requiring the eRA Commons User Name for all PIs will improve data quality. This is particularly important for applications proposing multiple PIs. This data field will be pivotal in assuring all named PIs have access to the appropriate data.
- **Form Page 2 (continued)**: The instructions for the Key Personnel section of Form Page 2 have been revised to accommodate multiple PIs.
- **Table of Contents (Form Page 3) & Research Plan Instructions**: The Research Plan has been revised to include a distinct section for a Multiple PI Leadership Plan (new Section I). This plan includes a description of the governance and organizational structure, including communication plans and procedures for resolving conflicts. It also includes a delineation of the shared administrative, technical, and scientific responsibilities for the PIs.

- **Personal Data Form Page** : This page has been revised to cover the collection of this demographic information for all PIs.
- **General Instructions Changes:** Changes have been made throughout the instructions to include appropriate guidance for multiple PIs.

Revised Requirements for Select Agent Research

The requirements of the Research Plan have been revised to include a new section dedicated specifically to Select Agent Research. This new section (G. Select Agent Research) is only required when applicable. Additionally, the Resource Format Page instructions have been revised to request specific information on the biocontainment resources available when applicable. Finally, the Select Agent Research section in Part III Policy/Assurance/Definitions has been revised to include additional informational websites.

Change in Business Process: Eliminating Biographical Sketch Subsection Limits

The requirements for the biographical sketch have been changed to eliminate the 2-page subsection limit for sections A&B. The entire biographical sketch continues to have a 4-page limit (including the table at the top of the first page); however, the 2-page subsection limit for sections A&B has been eliminated.

Removal of all Instructions and Data Requirements Specifically for Programs Transitioned to the SF424 (R&R)

As NIH continues to transition all funding mechanisms to electronic submission and the SF424 (R&R) application, the data requirements and instructions to the PHS398 will be changed accordingly. With this revision, all instructions and data requirements specific to SBIR and STTR applications (R43/R44 & R41/R42), AREA applications (R15s); and Conference applications (R13/U13s) have been removed.

A consolidated list of changes to each Form or Format Page follows:

Form Page 1 : Face Page (Rev. 4/06)

- New form page developed (Form Page 1-continued) to capture PI information for multiple PIs.
- Item 3h. The eRA Commons User Name (the unique name used to log into the system) is now a required for all PIs.
- Item 14, PI Signature Assurance has been removed.

Form Page 2 (Rev. 4/06):

- Instructions for Key Personnel have been revised to incorporate multiple PIs.
- The Disclosure Permission Statement applicable for SBIR/STTR applicants has been removed

Form Page 3 : Table of Contents (Rev. 4/06)

- The Table of Contents for the Research Plan has been revised to include 2 new sections—
Select Agents Research and Multiple PI Leadership Plan
- The Commercialization Plan item specific to SBIR/STTR applicants has been removed

Form Page 4 : Detailed Budget (Rev. 4/06)

- The Personnel Section has been revised to replace Type of Appointment & Percent Effort columns with Person Month columns (calendar, academic, and summer)
- The budget item for SBIR/STTR Fee has been removed

Form Page 5 : Budget for Entire Proposed Period of Support (Rev. 4/2006)

The budget item for SBIR/STTR Fee has been removed

Modular Budget Format Page (Rev. 4/06):

- Instructions have been modified for the Personnel Justification section to request effort devoted to the project using person months (calendar, academic, and summer)
- The budget justification section for SBIR/STTR Fee has been removed.

Resources Format Page (Rev. 4/06):

- Instructions revised to request information concerning biocontainment resources when Select Agent Research is proposed.

Checklist Form Page (Rev. 4/06):

- All SBIR/STTR-specific data fields and information have been removed
- Section 2. Assurance has been revised to include new PI Assurance

Key Personnel Format Page (Rev. 4/06) :

The column requesting annual effort has been modified to now reflect person months (calendar, academic, summer)

Personal Data Form Page (Rev. 4/06) :

Instructions have been revised to cover the collection of this demographic information for all PIs.

Biographical Sketch Format Page (Rev. 4/06):

Instructions have been revised to eliminate the 2-page subsection page limit for sections A&B. The entire biographical sketch still has a 4-page limit, including the table at the top of page one.

Other Support Format Page Example (Rev 4/06) :

Instructional text and the example have been modified to reflect effort measurements in person months (calendar, academic, summer).

Inquiries

Questions concerning this guide notice or any changes to the PHS 398 forms and instructions may be directed to:

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Office of Policy for Extramural Research Administration
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Telephone: (301) 435-0938
Email: GrantsPolicy@od.nih.gov

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