

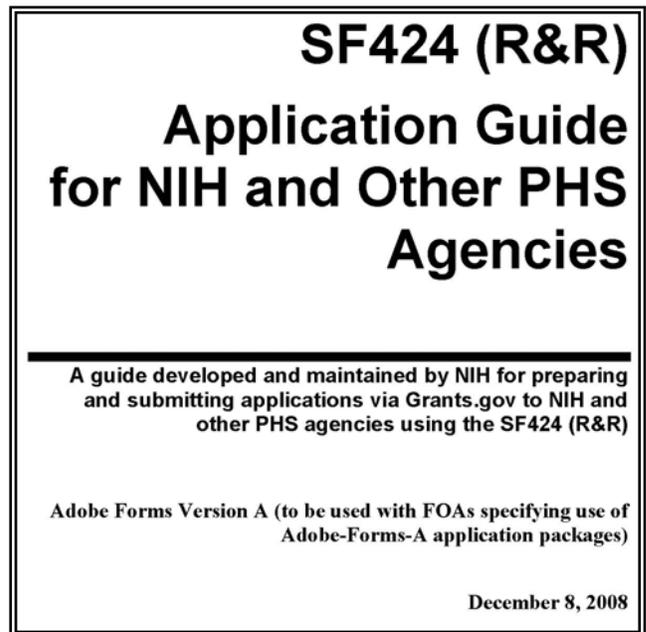
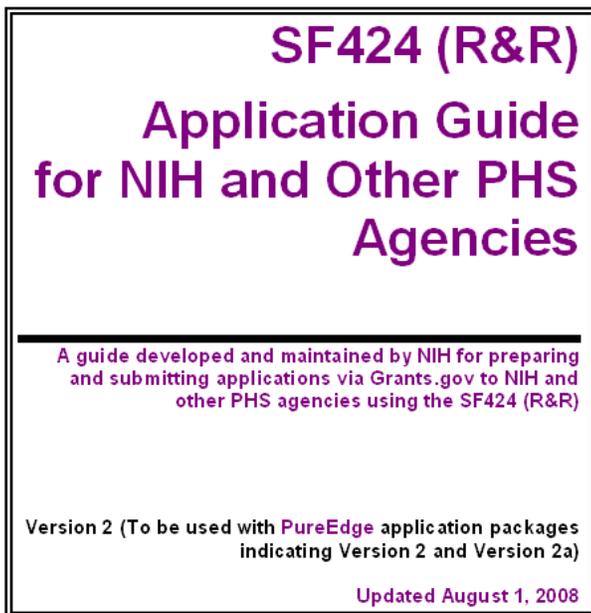


Summary of PHS SF424 Changes August & December 2008

Sponsored Projects Office
One Cyclotron Road, MS46R0125, Berkeley, CA 94720, USA Distributed December 2008 SPO NIH Training to Staff and PIs

This document summarizes the changes to the SF424 for PureEdge and to Adobe Forms. The section numbers and headings from the NIH Guidelines are here for your reference to the full guidelines. Full copies of the Guides are available at:

<http://grants.nih.gov/grants/funding/424/index.htm>



Questions regarding NIH policies and guidelines should be sent to:

Cynthia Ernest
Contracts Officer
LBNL Sponsored Projects
clernest@lbl.gov
ext 5938

Questions regarding a specific proposal should be addressed to the SPO Contracts Officer that supports your division.

The August 1, 2008 version of the SF424 Guide indicates changes are in purple. In fact, most of the information highlighted was changed in April 2008. The actual changes made in August are included here. December 8, 2008 changes to Adobe Forms are the same as the changes made in August, but now referencing Adobe FormsA instead of the Pilot program.

(Notes inside parens and italicized are from LBNL SPO)



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PART I Instructions for Preparing and Submitting an Application

Section 1.4 Interaction with PHS Staff

Before submission:

GrantsInfo@nih.gov and/or the Division of Receipt and Referral, Center for Scientific Review (CSR) is the correct staff to contact **to receive advice on preparing and submitting an application (e.g., format, structure).**

2.3 Software Requirements

2.3.1 Adobe Reader

In order to access, complete and submit applications, applicants need to download and install the Adobe Reader, **version 8.1.1 or later**. For minimum system requirements and download instructions, please see the [Grants.gov User Guide](#).

Please note that you must set the Adobe Reader's page layout options to "Continuous" instead of "Single Page" to ensure all features function properly. To do this, choose View > Page Layout, and then choose the "Continuous" option.

2.3.3 Special Instructions for Macintosh Users

With the conversion to Adobe Reader applications submissions there are no longer special instructions for Macintosh users.

2.4.3 Finding a Funding Opportunity Announcement (FOA) for Grants.gov Submission

(Instructions are clarified and expanded for "Find Grant Opportunities and "Apply for Grants." Refer to the full guidelines for navigation and screen print information.)

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2.7 “Resubmission” (Revised) Applications

(adds paragraph)

Acceptance of a resubmission application will not automatically withdraw the prior version. As of February 2008, eRA keeps all versions (e.g., 01, A1, A2) of a grant application active and provides an internal MAA (“Multiple Active Applications” flag for each application in an active cluster. The cluster allows applicants to identify quickly all versions of one application. If any version in a cluster is awarded, application will notice that all other applications within the cluster will be automatically withdrawn without any additional action by applicants or staff.

(Navigation instructions are clarified for both the AOR/SO and the PD/PI for viewing the assembled application and correcting errors. See full Guides for this information.)

3. Using the Grant Application Package

(Clarification about budgets in the “optional” section although one will be mandatory and only one can be used.)

4. Completing the SF424 Research and Related (R&R) Forms

4.1 Overview

(adds note about the “Check Package for Error” feature – in Adobe Forms only)



Note the highlighted fields required for submissions, and the “Check Package for Errors” button, only refer to requirements and errors in the actual Adobe Reader forms. They do not refer to requirements or data errors against PHS business processes. Those validations will be performed by the eRA Commons system after the application has been submitted.

On Adobe Forms, the required fields are highlighted in yellow and outlined in red.

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7. Type of Applicant

(the guidelines provided clarifying language; but LBNL uses “Higher Education” as the correct selection.)

Type of Application *(adds clarifying paragraphs)*

This field also affects how you complete Item 4. Federal Identifier. If “Type of Application” is “New”, you can leave the Federal Identifier field blank on the first submission attempt. However, the Federal Identifier field becomes a required field when submitting a Changed/Corrected application to address errors/warnings. When submitting a Changed/Corrected “New” application, enter the Grants.gov tracking number of the previous submission attempt (e.g. GRANT12345678). If you are unable to find the tracking number, enter “N/A”.

If “Type of Application” is “Renewal”, “Revision” or “Resubmission”, enter the IC and serial number of the prior application/award number (e.g. CA123456). For these types of applications, do not change the Federal Identifier field when submitting Changed/Corrected applications.

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4.5 Senior/Key Person Profile (Expanded) Component

(new instructions for Adobe Forms)

This component provides the ability to collect structured data for up to 40 Senior/Key Persons. Data must be entered for the first 40 individuals (PD/PI + 39 others) before the Additional Senior/Key Person Form Attachments section becomes available. The information for the PD/PI continues to be pre-populated from the SF424 (R&R) Cover component. See instructions in section 4.2 Cover Component if these fields are empty. Unless otherwise specified in an agency announcement, senior/key personnel are defined as all individuals who contribute in a substantive, meaningful way to the scientific development or execution of the project, whether or not salaries are requested. Consultants should be included if they meet this definition.

(changes for PureEdge application packages)

Two components are now available to collect information on Senior/Key persons. The original component continues to be called "Research & Related Senior/Key Person." The new component is titled: "Research & Related Senior/Key Person Expanded." Application packages will include one or the other, but never both. Eventually, only the expanded version will be used in application packages. Until that transition is complete, instructions are provided in this section for both components.

4.7 R&R Budget Component

A. Senior/Key Person

(adds clarification about Other Significant Contributors and Consultants)



Personnel listed as Other Significant Contributors who are not committing any specific measurable effort to the project should not be included in the Personnel section of the budget since no associated salary and/or fringe benefits should be requested for their contribution. Consultants designated as Senior/Key Persons in the Senior/Key Person Profile Component can be included in Budget Section A only if they are also employees of the applicant organization. Otherwise, consultant costs should be included in F.3 Consultant Services.

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F. Other Direct Costs

7. Alterations and Renovations

(adds clarification)

Note, costs for any Alterations and Renovations (A&R) were previously unallowable on applications from foreign institutions, international organizations and domestic applications with foreign subawards. However, an HHS policy change now allows for minor A&R (\leq \$500,000) on these applications.

When requesting minor A&R costs under this policy, please provide detailed information on the planned A&R in the budget justification.

5. Completing PHS398 Components

5.2 Cover Letter Component

(LBNL SPO has created a template for use by the PIs)

5.5 Research Plan Component

16. Letters of Support

(adds specifics about who should provide letters of support)

Attach all appropriate letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the grant application. Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project. For consultants, letters should include rate/charge for consulting services.

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PART II

Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan

5. Human Subjects Research Policy

5.4 IRB Approval

(adds a clarifying paragraph)

HHS human subject regulations at 45CFR46.101(f) require that each application for non-exempt HHS-supported human subject research be reviewed and approved by an IRB (see also <http://www.hhs.gov/ohrp/humansubjects/guidance/aprev.htm>). Only the date of approval of the application should be submitted to NIH. However, the IRB must ensure that any corresponding protocol(s) are consistent with the application, and must maintain documentation of IRB approval of all corresponding protocols, including those reviewed by consortium participants.

PART III

Policies, Assurances, Definitions, and Other Information

Human Subjects Research Definitions and Terms.

Coded.

(New)

Individuals who provide coded information or specimens for proposed research and who also collaborate on the research involving such information or specimens are considered to be involved in the conduct of human subjects research.

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