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

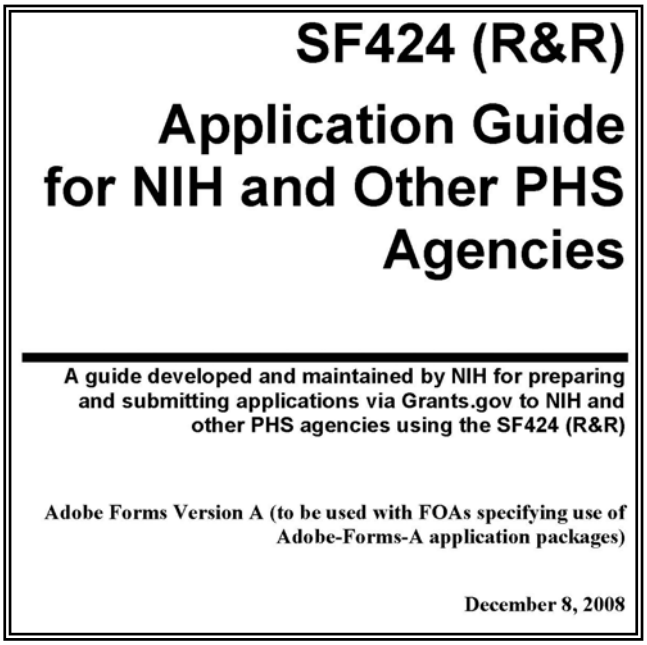
SF424 (R&R)

Application Guide for NIH and Other PHS Agencies

A guide developed and maintained by NIH for preparing and submitting applications via Grants.gov to NIH and other PHS agencies using the SF424 (R&R)

Version 2 (To be used with PureEdge application packages indicating Version 2 and Version 2a)

Updated August 1, 2008


SF424 (R&R)

Application Guide for NIH and Other PHS Agencies

A guide developed and maintained by NIH for preparing and submitting applications via Grants.gov to NIH and other PHS agencies using the SF424 (R&R)

Adobe Forms Version A (to be used with FOAs specifying use of Adobe-Forms-A application packages)

December 8, 2008

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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August 2008

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Distributed October 2008 SPO Process Meeting

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.)

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3. Using the Grant Application Package

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

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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 (≤$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.

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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.hhh.gov/ohrp/humansubjects/guidance/aplrev.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.

(Notes inside parens and italicized are from LBNL SPO)

NIH Transition to Adobe Forms

2008

2009

Small business and conference FOAs will use PureEdge forms for receipt dates on or before Jan. 7, 2009; and Adobe thereafter

OCT → NOV → DEC → JAN → FEB

NIH pilot of Adobe Forms (mid-late Oct.)
RFA-AI-08-020
RFA-DE-09-001
RFA-DE-09-002

Adobe forms for existing and new FOAs will be available in **early Dec.*** (Except for small business and conference FOAs)

Most submissions after Jan. 1, 2009 **must** use Adobe forms, with these **exceptions****

Adobe forms for SBIRs and R13/U13s will be available in **early Feb. 2009**

***New FOAs issued after September 1, 2008 might not contain application forms.**

→ Adobe forms will be made available for these FOAs in early Dec. 2008

→ Adobe forms for small business and conference FOAs will be available in early Feb. 2009

****Most FOAs with receipt dates on or after Jan. 1, 2009 must use Adobe forms, except…**

→ Small business applications (R41,R42,R43,R44) and conference grant applications (R13/U13) with Jan. 7, 2009 AIDS submission deadlines

→ All FOAs expiring on or before Jan. 31, 2009 that will continue to use PureEdge until the expiration date. See complete list on eSubmission Web Site at http://era.nih.gov/ElectronicReceipt/

eRA Commons Roles

A Signing Official (SO) role has the following privileges:

- Register the applicant institution in the eRA Commons.
- Create and update the institutional Profile (IPF).
- Create/delete/update all Commons accounts (except IAR and TRAINEE accounts).
  Note: The SO cannot modify a user's Personal Profile.
- Create affiliation of an existing PI and/or IAR Commons account.
- Submit electronic grant application(s) on behalf of the institution via Grants.gov (outside of eRA Commons), if also registered with Grants.gov as Authorized Organization Representative (AOR).
- View status of all grant applications originating from their institution and any errors or warnings that may have been triggered.
- View assembled image of submitted grant applications before they move on for further processing.
- Reject grant applications to address warnings or if some part of the application was lost or did not transfer correctly during the submission process due to a Grants.gov or Commons issue.
- View award information for all grants awarded to the institution. Note: Cannot view summary statement or priority score.
- Submit Just-in-Time information.
- Can View the following Training Grant related items: Trainee Roster, List of Grants, Grant Summary, Routing History, PDF formatted Appointments/Amendments/Terminations.
- Delegate Electronic Streamlined Noncompeting Award Process (eSNAP) edit authority to another user on behalf of the PI.
- Delegate submit authority for progress reports (eSNAPs) to the Principal Investigator (PI).
- Submit eSNAPs on behalf of the institution.
- Submit Final Progress Report
- This role should not be combined with PI role.

A Business Official (BO) role has the following privileges:

- Used with xTrain, a service to electronically manage Appointments for awarded Training Grants.
- Can View the following Training Grant related items: Trainee Roster, List of Grants, Grant Summary, Routing History, PDF formatted Appointments/Amendments/Terminations.
- Initiate, update, route and submit Termination Notices (only user authorized to submit TNs.)

A Principal Investigator (PI) role has the following privileges:

- Edit Personal Profile.
- Delegate edit authority of own Personal Profile authority to others.
- View status of all grant applications for which they are the designated PD/PI, including any errors or warnings that may have been triggered.
- View assembled image of submitted grant applications before they move on for further processing.
- View Study Section/Meeting Roster of the Review Group that will be reviewing your application.
- View Review outcome information and Summary Statements.
- View Notice of Award for all grants for which they are the designated PD/PI.
- Delegate xTrain Authority to ASST so they can perform same actions and receive same notifications as PI except for the ability to submit Appointments to Agency.

- Can View the following Training Grant related items using xTrain: Trainee Roster, List of Grants, Grant Summary, Routing History, PDF formatted Appointments/Amendments/Terminations.
- Initiate, update, route and submit Appointments, Re-Appointments and Amendments in xTrain.
- Initiate, update and route Termination Notices in xTrain.
- Initiate eSNAP.
- Delegate eSNAP edit authority.
- Submit eSNAP (if given the authority by SO).
- Delegate Status authority to others within the Institution so that they can see PI grant information (except Review outcome information and Summary Statement).
- This role should not be combined with SO role. Can be combined with IAR role.

A Trainee (TRAINEE) role has the following privileges:

- Used with xTrain, a service to electronically manage Appointments for awarded Training Grants.
- View his/her own PDF formatted Appointments/Amendments/Terminations and their Routing history.
- Update and route his/her own Appointments/Amendments/Terminations.

An Administrative Official (AO) Role has the following privileges:

- Create all accounts (**except** IAR, TRAINEE, and BO).
- Update only Commons accounts created by the AO.
- View status and award information for all institution grants. Note: Cannot view summary statement or priority score.
- Create affiliation of an existing PI or IAR Commons account and the institution.

  Note: The AO cannot modify the Institutional Profile.

An Account Administrator (AA) Role has the following privileges:

- Create/edit all Commons accounts (except IAR and TRAINEE accounts).

  Note: The AA cannot create/modify an Institutional Profile or user's Personal Profile.

An Assistant Role (ASST) has the following privileges:

- Edit own Personal Profile data.
- Edit PI's Personal Profile if delegated by PI.
- Edit PI's eSNAP data if delegated by PI.
- View PI Grant Status if delegated by PI.
- Perform PI xTrain functions (except submit to agency) if delegated by PI.

A Financial Status Report (FSR) Role has the following privileges:

- Submit Financial Status Reports on behalf of the institution.

  Note: An account with only the FSR role assigned only can perform FSR tasks. An account can include multiple roles, including that of FSR.

An Internet Assisted Review (IAR) Role has the following privileges:

- Edit own Personal Profile and Reviewer address data.
- Use Internet Assisted Review (IAR) to submit critiques and preliminary scores for applications to be reviewed at a meeting for which they are enabled. This role is granted by a Scientific Review Administrator and does not require Institution Affiliation.
- If affiliated with an institution, the reviewer can take advantage of other Commons features such as Status.

Change in New Investigator Policy Designed to Encourage Early Transition to Research Independence (from November 2008 Extramural Nexus)

An Early Stage Investigator (ESI) is a New Investigator who is within 10 years of completing a terminal research degree or of completing medical residency (or the equivalent). ESI applications will be identified and the career stage of the applicant will be considered at the time of review and award. NIH hopes that by providing a focus on ESIs, we will be able to directly encourage earlier application for NIH research grant support. Peer reviewers will be instructed to concentrate more on the proposed method of research and to expect less preliminary data than might be provided by an established investigator. In addition, many NIH institutes and centers will give special consideration to ESI applications; while in some cases, grant periods for ESIs may be longer. For additional details on this new policy please see NIH Guide Notice NOT-OD-08-121.

New Investigators can update degree information in their eRA Commons profile immediately, and after January 17, 2009, the Commons will be ready to accept residency completion dates as well. New investigators who do not yet have an eRA Commons account must work through the sponsored research office or its equivalent at their institution in order to establish an account and complete a profile. Investigators who enter degree and residency completion dates will be notified of their ESI status by e-mail.

- Click here to find out more about updating your personal profile
- Work through your sponsored research office if you need an eRA Commons account
- After January 17, return to your profile to add your residency completion date

Implementing the Early Stage Investigator Policy: Updating eRA Commons Profiles to Include Degree and Residency Completion Dates

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Notice Number: NOT-OD-09-021

Key Dates
Release Date: November 21, 2008

Issued by
National Institutes of Health (NIH), (http://www.nih.gov)

Early Stage Investigator Policy

The NIH recently announced a change in NIH New Investigator policies designed to encourage early transition to independence. Under this policy, New Investigators within ten years of completing their terminal research degree or within ten years of completing their medical residency will be designated Early Stage Investigators (ESIs). Traditional NIH research grant (R01) applications from ESIs will be identified and the career stage of the applicant will be considered at the time of review and award. More information on this policy is available in related notices in the NIH Guide, establishing ESI as a category of new investigators, and revising policies on new investigators and ESIs, and on the New and Early Stage Investigator website at http://grants.nih.gov/grants/new_investigators/index.htm

Need to Establish eRA Commons Profiles and to Update Degree and Residency End Dates

In order to implement this modified policy, all New Investigators must update their eRA Commons profiles to ensure that they are given appropriate consideration for R01 applications for February, 2009 due dates and beyond. The degree date information requested in the profile and eventually the date of completion of medical residency will be used to determine ESI eligibility. Once degree and residency completion dates are entered into eRA Commons, individuals who are eligible for ESI or New Investigator status will be notified of their eligibility by email.

New investigators who do not yet have an eRA Commons account should work through the sponsored research office or its equivalent at their institution to establish an eRA Commons account. Investigators who already have an account should update degree information at http://commons.era.nih.gov/commons. The eRA Commons will be ready to accept the completion date of medical residency after January 17, 2009.

It should be noted that an individual will be identified as New Investigator by determining whether he/she has previously competed successfully for a significant NIH research grant. Please see the definition of New Investigator on the New and Early Stage Investigator Website at http://grants.nih.gov/grants /new_investigators/index.htm
The New Investigator Checkbox currently in the PHS398 and Standard Form 424 will be removed.

NIH encourages all investigators to keep information in their Commons profiles as current as possible.

Requests for Extension of ESI Eligibility

Within a few weeks, instructions for requesting an extension of the period of ESI eligibility will be announced in the NIH Guide for Grants and Contracts and will be posted on the New and Early Stage Investigator Website at http://grants.nih.gov/grants/new_investigators/index.htm. The NIH will consider extending the period of ESI eligibility to accommodate special circumstances including but not limited to medical concerns, disability, family care responsibilities, extended periods of clinical training, or active duty military service.

Inquiries

Direct inquiries regarding ESI Policies to esinih@od.nih.gov

If you have questions about data entry or access to the eRA Commons, please look at the Frequently Asked Questions on the eRA Commons at https://commons.era.nih.gov/commons/faq.jsp. The office of sponsored research at your institution may be helpful or you can contact the eRA Help Desk at commons@od.nih.gov or by phone to 1-866-504-9552.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, RealPlayer, Video or Flash files, see Help Downloading Files.

Prepare Now for the Switch From PureEdge to Adobe
(from November 2008 Extramural Nexus)

In September 2008, the *NIH Extramural Nexus* announced the upcoming arrival of new Adobe-based application forms for electronic submissions. The article alerted readers that most electronic submissions to NIH on or after January 1, 2009, must use the new Adobe-based forms (see the full Adobe transition timeline for more dates and details). As the winter holidays rapidly approach, we realize that our January transition date is right around the corner. Consequently the time to prepare for the switch from PureEdge to Adobe is NOW!

Adobe-based application packages will become available after the first week of December 2008. Applicants should download the new application from the FOA for which they are applying after December 5, 2008.

We remind you that the new Adobe-based forms require very specific software. To ensure a smooth transition, everyone who will work on an application must download Adobe Reader version 8.1.3 or later – available at no cost from Grants.gov – and use it to open and complete their application(s). **Non-compatible versions of Adobe Reader will prevent successful submission to Grants.gov; make sure to install compatible software before you begin your application!**

Detailed information about the transition and additional resources can be found at the following links:

- Resources for the Adobe Transition
- Electronic Application Process
- Grants.gov Applicant Resources

NIH initially intended to accommodate multiple form changes in conjunction with January's move to Adobe; however, a delay in receiving the revised forms has prompted us to modify our schedule. (For a list of planned form changes, see Guide Notice # NOT-OD-08-073). **This means that applicants will need to return to their respective FOAs in April to download the latest version of the Adobe-based application forms for receipt dates of May 2009 and beyond.**

Remember: Although the software has changed, the electronic submission process has NOT. The new Adobe forms will have the same look and feel as PureEdge forms, and the overall process of finding opportunities, preparing forms and submitting applications will remain the same.