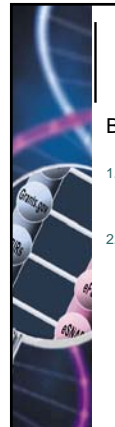


NIH Transition to the SF424 (R&R) Application & Electronic Submission Plus A Walk Through The SF424 (R&R)

Megan Columbus, Program Manager
Electronic Receipt of Grant Applications
And
Marcia Hahn
Director, Division of Grants Policy

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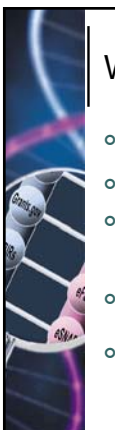


NIH's Electronic Receipt Goal

By the end of September 2007, NIH plans to:

1. Require electronic submission through Grants.gov for all NIH grant applications
2. Transition from the PHS 398 application form to SF424 family of forms data set
 - SF424 Research and Research-Related (SF424 (R&R))
 - SF424 Discretionary (of limited use for NIH)

Announced in the NIH Guide, Aug. 19, 2005:
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-067.html>



Why submit electronically?

- Eliminates the burden of paper-based data collection
- Improves data quality
- May allow NIH to shorten the cycle from application receipt to award
 - **AREA grants – An early win!**
- Reduces scanning, printing, and data-entry costs
- Grant image is consistent, clear and in color

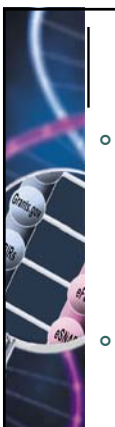
3



Why Grants.gov?

- The Federal government's single, online portal for any person, business, or State, Local and Tribal government to electronically:
 - [Find](#) Grant Opportunities
 - [Apply](#) for Grant
- A cross-agency initiative involving
 - 900 grant programs
 - 26 grant-making agencies
 - Over \$350 billion in annual awards


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Why transition to SF424 family of forms?

- SF424 consolidates forms currently used by Federal grant-making agencies
 - Applicants can use standard forms regardless of the program or agency to which they are applying.
 - Reduces administrative burden on the Federal grants community.
- SF424 (R&R) is the government-wide data set for research grant applications

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Why transition now?

- **Public Law (PL) 106-107**
 - Federal Financial Assistance Management Improvement Act of 1999
 - Improve the effectiveness and performance of Federal financial assistance programs
 - Simplify Federal financial assistance **application** and reporting requirements
 - Improve the delivery of services to the public
- **President's Management Agenda (2002)**
 - "Agencies to allow applicants for Federal Grants to apply for, and ultimately manage, grant funds online through a common web site, simplifying grants management and eliminating redundancies . . ."

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Why transition now?

- OMB has set the following FY 2006 Goal for Agencies: Post 75% of Funding Opportunities in Grants.gov "Find" on "Apply"
- The PHS 398 OMB clearance expires in September 2007

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This is a huge transition for all of us!

- The simultaneous transition to electronic application submission and a new set of application forms is a huge initiative for NIH with an aggressive time table
- It involves:
 - Numerous funding mechanisms
 - Tens of thousands of applications ranging widely in size and complexity
- The transition relies upon many pieces for its success:
 - Technical development of eRA and Grants.gov systems
 - Trans-agency resolution of policy and operational issues
 - Lots of communications, training and outreach
 - Acceptance of change by NIH staff
 - Acceptance of change by our research partners in the extramural community.

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Requires Systems Working Together

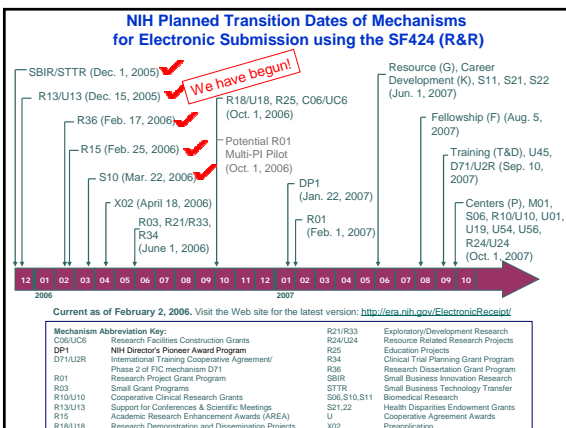
- Grants.gov – the Federal government's single on-line portal to find and apply for Federal grant funding.
- eRA Commons – the NIH electronic Research Administration system that allows applicants/grantees to electronically receive and transmit application and award information.
 - Used by NIH and other HHS components.

Important! Each system has its own registration requirements and validation process.

NIH's Transition Strategy

- NIH will transition by individual research program/funding mechanism
- ALL applications in response to these announcements for transitioned mechanisms will require electronic submission through Grants.gov on the 424 family of forms
- Mechanisms not yet transitioned will continue to require submission on PHS 398 on paper or through service providers
- NIH will announce plan to transition mechanisms in NIH Guide for Grants and Contracts

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Completed Transitions

- December 1, 2005: Small business (SBIR/STTR)
 - Over 1800 applications received
- December 15, 2005: Conference grants (R13)
 - Over 150 applications received
- February 17, 2006: Dissertation Grants (R36)
- February 25, 2006: AREA grants (R15)
- March 22, 2006: Shared Instrumentation (S10)

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Registration Requirements

- Registration in both Grants.gov and eRA Commons is required for electronic submission
- Separate processes that can be done simultaneously
- Must be completed **prior** to application submission
- Failure to complete required registrations prior to submission may result in delay of review assignment and funding consideration

It is critical for institutions to begin this registration process at least 2 - 4 weeks before applications are due!

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Registration Requirements: Grants.gov

- **Applicant organizations** must complete one-time only registration
- Principal Investigators do not need to register with Grants.gov
- Good for electronic submission to all Federal agencies
- Detailed instructions at: <http://grants.gov/GetStarted>
 - Grants.gov registration requires institutions to:
 - Obtain a Data Universal Numbering System (DUNS) number
 - Register in Central Contractor Registry (CCR)
 - * New organizations should allow extra time for this step
- Registration not required to find funding opportunity or download application package, only to submit completed application

It is critical for institutions to begin this registration process at least 2 - 4 weeks before applications are due!

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Registration Requirements: eRA Commons

- Applicant institutions must complete one-time only registration.
- Principal Investigators (PIs) must work through their institutions to register.
 - The PI must hold a PI account and be affiliated with the applicant organization.
 - PIs currently registered only for Internet Assisted Review (IAR) must work through their institutions for full eRA Commons registration.
- PI and Signing Official (SO) need separate accounts in eRA Commons since both need to verify the application.

It is critical for institutions to begin this registration process at least 2-4 weeks before applications are due!

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Registration Requirements: eRA Commons (cont.)

- Organizations must include a DUNS number in their institutional profile that matches the DUNS number on the submitted application.
- NIH will consider starting the eRA Commons registration process **at least two weeks in advance** of the submission date a "good faith" effort to prepare for electronic submission. Applicants that make a "good faith" effort to register, will not be penalized for any NIH-caused registration processing delay.
- See <http://era.nih.gov/ElectronicReceipt/preparing.htm> for additional information.

It is critical for institutions to begin this registration process at least 2-4 weeks before applications are due!

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Submission Methods

Applicant organization can submit applications to NIH through Grants.gov in one of two ways:

1. Direct submission - using PureEdge Viewer
2. System-to-system – using (XML) data stream to communicate with Grants.gov
 - Can be created by institution OR
 - Institution can establish an agreement with a commercial Service Provider
<http://era.nih.gov/ElectronicReceipt/sp.htm>


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Software Requirements

- PureEdge viewer downloaded (free) from Grants.gov site at <http://www.grants.gov/DownloadViewer>
- PDF generation software
 - Grants.gov lists some available tools and software <http://www.grants.gov/assets/PDFConversion.pdf>.
- MAC users will need to use PC emulation software or download free CITRIX client application to take advantage of the CITRIX service offered by Grants.gov in partnership with NIH. <http://www.grants.gov/MacSupport>
 - PureEdge has committed to providing a platform independent viewer by November 2006.

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New Business Process: Funding Announcements

- Funding Opportunities Announcements (FOAs) will continue to be posted in the NIH Guide and Contracts (<http://grants2.nih.gov/grants/guide/>)
 - Button added to the NIH Guide announcements allowing applicants to access the Grants.gov application package directly from the NIH Guide 
 - NIH will continue to use RFAs and PAs, but all solicitations will also be referred to as FOAs in Grants.gov
- FOAs will simultaneously be posted to Grants.gov along with the appropriate application package
 - Note that you must search Grants.gov by opportunity number rather than CFDA number for NIH opportunities.

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New Business Process: Funding Announcements (cont.)

- Not all components will be used for every FOA
- Agencies “construct” application packages for each FOA
- NIH will use several “standard” packages
- The FOA will indicate which components are required and which are optional
- Each FOA will have the appropriate application package attached
- This specific application package **MUST** be used to apply for the accompanying solicitation.
 - Some fields of application are pre-filled from announcement

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New Business Process: Funding Announcements (cont.)

- Funding Opportunity Announcements will be posted in Grants.gov “Apply”, generally 2 months before the submission date.
 - Release Date – the date an application is posted. Posting announcement allows downloading of application package and the ability to start working on the application.
 - Opening Date - the first date the completed application can be submitted to Grants.gov.

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Electronic Submission: How it Works

Applying for Grants at Grants.gov:

- Step 1: Search for & identify funding opportunity in the NIH Guide for Grants and Contracts or on Grants.gov
- Step 2: Download the grant application package.
- Step 3: Complete the application. Be sure to save a local copy. **Route through your own institutional review & approval process.**
- Step 4: The Authorized Organizational Representative (AOR) submits application to Grants.gov either directly or through a Service Provider. **All required registrations must be completed prior to submission.**

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Electronic Submission: How it Works (cont.)

- Step 5: Grants.gov performs basic form validation and virus check on submitted application.
- Step 6: Track the status of the submitted application package at Grants.gov until you are notified via email that NIH has received it.
- Step 7: eRA software performs NIH business rule validation on submitted application.
- Step 8: NIH notifies Principal Investigator (PI) and Signing Official (SO) by email to check the eRA Commons for results of NIH validations check.

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Electronic Submission: How it Works (cont.)

- Step 9: The PI and SO find out if the grant application passed or failed the rule check, and:
 - If it passed, PI and SO must verify the application in eRA Commons to complete the application submission process.
 - If it failed, all errors must be corrected and the entire corrected application must be submitted to Grants.gov.
- Step 10: After verification, the eRA Commons saves the data and grant image, and NIH begins processing the application.
- Step 11: Applicants can track the progress of their application in eRA Commons.

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On-Time Submission*

- On-time submission has 2 elements:
 1. Application accepted by Grants.gov by 8:00pm ET on the submission date
 2. Verify application image within 2 days of availability in the NIH Commons
- During initial transition period, NIH validation errors may be corrected within 1 week period after receipt date

* NIH's late application policy still in effect

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Expected Turnaround Times

- Registration – can take several weeks to complete; start 2-4 weeks in advance of submission date
- Grants.gov response to application submission – generally within hours, up to 2 business days
- eRA Commons response to application submission – generally within hours, up to 2 business days
- Principal Investigator (PI) and Authorized Organization Representative (AOR)/Signing Official (SO) Verification of application - within 2 business days of availability in eRA Commons

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Guiding Principles:

- NIH will not hold applicants accountable for Grants.gov or NIH system problems
- Applicants are expected to:
 - Complete required registration processes prior to submission
 - Complete both steps of application submission in a timely way
 - Submission to Grants.gov
 - Application verification

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Features of the SF424 (R&R)

- The SF424 (R&R) is an application form that is comprised of common data elements developed for use by Federal agencies funding Research and Research-Related programs
- Also provides a consistent electronic submission process through Grants.gov

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Features of the SF424 (R&R) (cont.)

- A complete application to NIH will include a combination of (R&R) components & PHS398 components
- The applicant **must** complete the application using the package attached to that particular FOA (*Information is drawn from the specific FOA and used in the forms*)
- Applicants can *not* use any sample form packages or form packages from other announcements
- The applicant will complete data entry in all necessary components and upload appropriate attachments

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Features of the SF424 (R&R) (cont.)

- SF424 (R&R) Components include:
 - SF424 (R&R)—*An application cover component*
 - Research & Related Project/Performance Site Location (s)
 - Research & Related Other Project Information
 - Research & Related Senior/Key Person
 - Research & Related Budget
 - Research & Related Personal Data (*NIH will not use*)
 - R&R Subaward Budget Attachment Form
 - SBIR/STTR Information

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Features of the SF424 (R&R) (cont.)

- NIH requires additional data collection to accommodate the unique information required for review of its biomedical research portfolio. Therefore, NIH has also developed agency-specific components (titled PHS398):
 - PHS 398 Cover Letter File
 - PHS 398 Cover Page Supplement (*supplements the R&R Cover*)
 - PHS 398 Modular Budget
 - PHS 398 Research Plan
 - PHS 398 Checklist
- Why call them PHS398?
 - Needed a generic term since other HHS agencies will use
 - It's the OMB-cleared data collection instrument that gives us the authority to request these additional data elements

Features of the SF424 (R&R) (cont.)

- Application components include specific data fields as well as multiple attachments
- Most attachments are text
- NIH will require PDF for text attachments
 - Attachments can be generated using any word processing software but will need to be converted to PDF before they can be attached to the actual application form
 - Do not include headers or footers in the text pages
 - See Tips & Tools page for other PDF Helpful hints

Features of the SF424 (R&R) (cont.)

- After submission, the **eRA system** will:
 - Generate a Table of Contents
 - Assemble the grant image
 - Include headers (PI name) & footers (page numbers) on all pages
- Applicants (*PD/PI & Authorized Organizational Representative*) will review and verify this grant image in the eRA Commons

Features of the SF424 (R&R): Application Guide

- NIH has developed 2 Application Guides specific to the SF424 (R&R): 1) General Instructions; 2) General +SBIR/STTR
- Includes instructions that are imbedded in the actual forms as well agency-specific instructions
- Agency-specific instructions denoted with the HHS Logo
- Documents have same part structure as PHS 398 Instructions:
 - Part I: Instructions for Preparing and Submitting an Application
 - Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan
 - Part III: Policies, Assurances, Definitions

SF424 (R&R) Components

- Application Package Header
- SF424 (R&R)—*An application cover component*
- Research & Related Project/Performance Site Location (s)
- Research & Related Other Project Information
- Research & Related Senior/Key Person
- Research & Related Budget
- R&R Subaward Budget Attachment Form
- SBIR/STTR Information

Grant Application Package

Opportunity Title: Small Business Innovation Research Program Parent Ann
 Opportunity Agency: National Institutes of Health
 CFDA Number: 97.061
 CFDA Description: Innovations in Applied Public Health Research
 Opportunity Number: PHS0606
 Competition ID:
 Opportunity Open Date: 11/07/2005
 Opportunity Close Date: 01/04/2006
 Agency Contact: GrantsInfo
 Telephone: (301) 435-6714
 Email: GrantsInfo@nih.gov

This opportunity is only open to organizations, applicants who are submitting grant applications on behalf of a company, state, local or tribal government, academia, or other type of organization.

Mandatory Completed Documents for Submission

Optional Documents

Component: SF424 (R&R)— A Cover Component

- Similar to the PHS398 Face Page
- Provides general information about the applicant organization, contact information for the **PD/PI** and **Authorized Organizational Representative**
- Provides application-specific information (type, title etc)

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SF424 (R&R)—A Cover Component: A Few Data Issues

- **Item 1, Type of Submission**
 - Pre-application—instructed not to use unless specifically noted in FOA
 - Changed/Corrected Application—To be used only when correcting an application that failed system validations. This is NOT a resubmission (amendment).
- **Item 5, Applicant Information:** This is for the applicant **organization**

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SF424 (R&R)—A Cover Component: A Few Data Issues

- **Item 5, Organizational DUNS:** Must match DUNS in eRA Commons profile for Applicant Institution
 - AOR should verify DUNS in Commons profile before submission
 - Use Organizational DUNS (not any DUNS for a specific individual)
 - If Organization has multiple DUNS, pick a single one for grants

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SF424 (R&R)—A Cover Component: A Few Data Issues

- **Item 8, Type of Application--New Terminology**
 - New is the same
 - **Resubmission** is equivalent to a Revision (a revised or amended application)
 - **Renewal** is equivalent to a Competing Continuation
 - **Continuation** is equivalent to a Progress Report. For the purposes of NIH and other PHS agencies, the box for Continuation will **not** be used and should **not** be checked.
 - **Revision** is somewhat equivalent to a Competing Supplement
- Terminology cross-walk provided in instructions

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SF424 (R&R)—A Cover Component: A Few Data Issues

- **Item 10, CFDA Number & Title**
 - CFDA = *Catalog of Federal Domestic Assistance*
 - Fields are pre-filled based on the specific announcement
 - Fields will be blank for applications in response to a FOA that include multiple CFDA
 - When multiple CFDAs are listed in an announcement, a CFDA will be assigned by the eRA system once a specific Institute assignment is made

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Project/Performance Site Locations

RESEARCH & RELATED Project/Performance Site Location(s)

Project/Performance Site Primary Location

Organization Name:

* Street: Street2:

* City: County: * State: * ZIP Code: * Country:

Project/Performance Site Location 1

Organization Name:

* Street: Street2:

* City: County: * State: * ZIP Code: * Country:

Additional Location(s):

OMB Number: 4040-0011
Expiration Date: 04/30/2008

Component: Research and Related Project/Performance Site Locations

- Equivalent to the PHS398 Form Page 2 Performance Site section
- Collects individual data for up to 8 locations
- > 8 locations information is provided in an attachment (*not structured data, just text*)
- Format for the >8 attachment available on SF424 (R&R) Forms Page: <http://grants.nih.gov/grants/funding/424/index.htm>

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RESEARCH & RELATED Other Project Information

Other Project Information

1. * Are Human Subjects Involved? Yes No

1.a. If YES to Human Subjects is the IRB review Pending? Yes No

IRB Approval Date: _____

Exemption Number: 1 2 3 4 5 6

Human Subject Assurance Number: _____

2. * Are Vertebrate Animals Used? Yes No

2.a. If YES to Vertebrate Animals is the IACUC review Pending? Yes No

IACUC Approval Date: _____

Animal Welfare Assurance Number: _____

3. * Is proprietary/privileged information included in the application? Yes No

3.a. * Does this proposal have an actual or potential impact on the environment? Yes No

3.b. If yes, please explain: _____

3.c. If the project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? Yes No

3.d. If yes, please explain: _____

3.e. * Does this project involve activities outside the U.S. or partnership with International Collaborator? Yes No

4. Optional Explanation: _____

5. Project Summary/Abstract

6. Project Narrative

7. Bibliography & References Cited

8. Facilities & Other Resources

9. Equipment

10. Other Attachments

OMB Number: 4240-0001
Expiration Date: 06/30/2008

Component: Research and Related Other Project Information

- Includes information on involvement of Human Subjects, Vertebrate Animals, Environmental Impact, Foreign Involvement
- Includes separate PDF attachments for
 - Project Summary/Abstract (*Description*)
 - Project Narrative
 - NIH will use this upload for the "Relevance" section of the Abstract
 - Separate component developed for Research Plan
 - Bibliography & References (*previously section G. Literature cited*)
 - Facilities & Other Resources
 - Equipment resources

Equivalent to PHS 398 Resources Format Page 51

RESEARCH & RELATED Senior/Key Person Profile

Senior/Key Person Profile

PROFILE - Project Director/Principal Investigator

First Name: _____ Middle Name: _____ Last Name: _____ Suffix: _____

Professional Title: _____ Department: _____

Organization Name: _____ Street: _____

City: _____ State: _____ Zip Code: _____ Country: _____

Phone Number: _____ Fax Number: _____ E-Mail: _____

Credential: e.g. Agency type: _____

* Project Role: _____ Other Project Role Category: _____

Health Biographical Status:

Additional Current & Pending Support:

PROFILE - Scientific Person

First Name: _____ Middle Name: _____ Last Name: _____ Suffix: _____

Professional Title: _____ Department: _____

Organization Name: _____ Street: _____

City: _____ State: _____ Zip Code: _____ Country: _____

Phone Number: _____ Fax Number: _____ E-Mail: _____

Credential: e.g. Agency type: _____

* Project Role: _____ Other Project Role Category: _____

Health Biographical Status:

Additional Current & Pending Support:

Additional Scientific Person Profiles:

Additional Biographical (Scientific) Person Profiles:

Additional Current and Pending Support:

Component: Research and Related Senior/Key Person

- Captures personal profile information on the PD/PI, Key Personnel, and Other Significant Contributors
- Captures structured data for 8 individuals (PI and 7 others)
- > 8 information is provided in an attachment (*not structured data, just text*)
- Format for the >8 attachment available on SF424 (R&R) Forms Page: <http://grants.nih.gov/grants/funding/424/index.htm>

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Component: Research and Related Senior/Key Person (cont.)

- **Credential:** Must enter the eRA Commons User Name—For the PD/PI, this is a **mandatory** field for NIH submissions. (#1 Validation Failure to date)
- Biosketch is attached for each person
 - Same data requirements exist; however, page limits slightly change to just 4 pages
 - Eliminating the 2 page limit for subsections
- Note, Attachment for **Current & Pending Support** (a.k.a. *Other Support*) will not be used at time of submission unless specified in FOA. For most applications, this will continue to be a Just-In-Time submission

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Component: Research and Related Budget, Sections A & B

- Personnel separated into 2 sections
- A. Senior/Key Person
 - Allows 8 as named individuals & structured data
 - > 8 information is provided in an attachment (*not structured data, just text*)
 - Info for PD/PI must be entered even if \$ = 0
- B. Other Personnel
 - Postdocs, Grad Students, Undergrads: captures # only
 - NIH will request more detail in Budget Justification

Component: Research and Related Budget, Sections A & B

- Business Process Change from Percent Effort to Person Months
 - Must enter either Calendar, Academic and/or Summer for all Senior/Key Persons
 - NIH will be incorporating this business process change throughout-- Other Support documentation; Interim change to PHS398 & PHS2590 Progress Report in process

Component: Research and Related Budget, Sections C - E

- C. Equipment
 - Allows itemization of up to 10
 - > 10 total dollars are inserted in line 11; however, the details are provided in an attachment
- D. Travel
 - R&R separates out Domestic & Foreign
 - This will not change any NIH policy/practice. We will continue to award as a single category
- E. Participant/Trainee Support Costs
 - Will not be used by NIH unless specifically noted in an announcement
 - Tuition Remission will continue to included in section F. Other Direct Costs

Component: Research and Related Budget, Sections F - K

- o F. Other Direct Costs
 - Itemizes Supplies, Publication Costs, Consultants, ADP/Computer Services, Consortium Costs, Equipment or Facility Rental/User Fees, Alterations & Renovations
 - Have included agency-specific instructions to use this section to also account for patient care costs & tuition remission
- o G. Total Direct Costs (A – F)
- o H. Indirect Costs
- o I. Total Costs
- o J. Fee
- o K. Budget Justification—a PDF text attachment
- o **Next Period** Button: At the top of the last budget page. All required data field in this component must be entered before this button is available. This includes the Budget Justification.

Component: Research and Related Budget, General Notes

- o Applicant prepares a detailed budget for every budget period
- o *There is no summary budget page like the PHS398 Form Page 5*
- o A detailed Cumulative budget is system-generated

R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

Instructions: On this form, you will attach the R&R Subaward Budget files for your grant application. Complete the subawardee budget(s) in accordance with the R&R budget instructions. Please remember that any files you attach must be a Pure Edge document.

[Click here to extract the R&R Subaward Budget Attachment](#)

Important: Please attach your subawardee budget file(s) with the file name of the subawardee organization. Each file name must be unique.

1) Please attach Attachment 1	Add Attachment	Delete Attachment	Name Attachment
2) Please attach Attachment 2	Add Attachment	Delete Attachment	Name Attachment
3) Please attach Attachment 3	Add Attachment	Delete Attachment	Name Attachment
4) Please attach Attachment 4	Add Attachment	Delete Attachment	Name Attachment
5) Please attach Attachment 5	Add Attachment	Delete Attachment	Name Attachment
6) Please attach Attachment 6	Add Attachment	Delete Attachment	Name Attachment
7) Please attach Attachment 7	Add Attachment	Delete Attachment	Name Attachment
8) Please attach Attachment 8	Add Attachment	Delete Attachment	Name Attachment
9) Please attach Attachment 9	Add Attachment	Delete Attachment	Name Attachment
10) Please attach Attachment 10	Add Attachment	Delete Attachment	Name Attachment

OMB Number: 4040-0001
Expiration Date: 04/30/2008

Component: R&R Subaward Budget Attachment Form

- o Used for detailed budget from any consortium grantee
- o Consortium grantee(s) must have PureEdge installed
- o Allows up to 10 separate budget attachments—one for each consortium grantee
- o Applicant sends the R&R budget component to the consortium grantee for completion; it is returned to the applicant; applicant attaches it in this component
- o Applicant still needs to include the total costs for all consortiums in their own detailed budget, Section F.5

SBIR/STTR Information

OMB Number: 0025-0001
Expiration Date: 09/30/2007

*Program Type (select only one)
SBR STTR

SBIR (See agency-specific instructions to determine whether a particular agency accepts a single submission for both SBIR and STTR)

*Mentor/STTR Type (select only one)
Phase I Phase II

Fast Track (See agency-specific instructions to determine whether a particular agency participates in Fast Track)

Questions 1-7 must be completed by all SBIR and STTR Applicants:

Yes/No

* 1. Do you certify that at the time of award your organization will meet the eligibility criteria for a small business as defined in the funding opportunity announcement?

* 2. Does this application include subcontracts with Federal laboratories or any other Federal Government agencies?
* If yes, insert the names of the Federal laboratories/agencies.

* 3. Are you located in a HUBZone? To find out if your business is in a HUBZone, use the mapping utility provided by the Small Business Administration at its web site: <http://www.sba.gov>

* 4. Will all research and development on the project be performed in the United States?
* If no, provide an explanation in an attached file.

* 5. Has the applicant and/or Program Director/Principal Investigator submitted proposals for essentially equivalent work under other Federal program solicitations or received other Federal awards for essentially equivalent work?
* If yes, insert the names of the other Federal agencies.

* 6. Disclosure Permission Statement: If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contracting with you for similar technologies, services?
* Attach file.

* 7. Commercialization Plan: If you are submitting a Phase I or Phase II Fast Track Application, include a Commercialization Plan in accordance with the agency announcement and/or agency specific instructions.

SBIR/STTR Information
Page 1

SBIR/STTR Information

OMB Number: 0025-0001
Expiration Date: 09/30/2007

SBIR-Specific Questions:
Questions 8 and 9 apply only to SBIR applications. If you are submitting ONLY an STTR application, leave questions 8 and 9 blank and proceed to question 10.

Yes/No

* 8. Have you received SBIR Phase II awards from the Federal Government? If yes, provide a company commercialization history in accordance with agency-specific instructions using this attachment.
* Attach file.

* 9. Will the Project Director/Principal Investigator have his/her primary employment with the small business at the time of award?


STTR-Specific Questions:
Questions 10 and 11 apply only to STTR applications. If you are submitting ONLY an SBIR application, leave questions 10 and 11 blank.

Yes/No

* 10. Please indicate whether the answer to BOTH of the following questions is TRUE:
 (1) Does the Project Director/Principal Investigator have a formal appointment or commitment either with the small business directly (as an employee or a contractor) OR as an employee of the Research Institution, which in turn has made a commitment to the small business through the STTR application process, AND
 (2) Has the Project Director/Principal Investigator devoted at least 10% effort to the proposed project?

* 11. In the past research and development proposed in this project, does the small business perform at least 40% of the work and the research institution named in the application perform at least 10% of the work?


SBIR/STTR Information
Page 2



Component: PHS 398 Cover Page Supplement

- Companion form to the (R&R) Cover Component
- For the PI, includes New Investigator Code & Degree fields (*Note, PD/PI info at the top is pre-filled. Provided here for reference only*)
- Includes Clinical Trial & Phase-III defined clinical trial indicators
- For the Business Official Contact, includes complete contact information (*title & mailing address missing from section 5 of the R&R Cover*)
- Includes Human Embryonic Stem Cells section

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PHS 398 Modular Budget, Periods 1 and 2

PHS 398 Modular Budget, Periods 1 and 2

Budget Period: 1

A. Direct Costs

B. Indirect Costs

C. Total Direct and Indirect Costs (A + B)


Budget Period: 2

A. Direct Costs

B. Indirect Costs

C. Total Direct and Indirect Costs (A + B)


PHS 398 Modular Budget



Component: PHS 398 Modular Budget

- Provides data entry for each budget period for
 - A. Direct Costs
 - DC less consortium F&A
 - Consortium F&A
 - Total DC
 - B. Indirect Costs Calculation section
 - C. Total Costs (A + B)
- Cumulative Budget is system-generated
- Budget Justification PDF text attachments for Personnel, Consortium and Other

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PHS 398 Research Plan


PHS 398 Research Plan

1. Application Type

2. Research Plan Attachments

3. Other Research Plan Sections


PHS 398 Research Plan



Component: PHS 398 Research Plan

- Separate PDF attachments for each section (*designed to maximize benefits of system validations & to accommodate bookmarking of the image*)
- Same formatting requirements in the PHS398 continue here—margins, page limits, etc
- Appendix Material
 - Allows up to 10 separate attachments
 - Will be stored separately in the eRA Grant Folder, not as a part of the main application grant image
 - Will be accessible to appropriate NIH staff and peer reviewers

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Component: PHS 398 Research Plan—Helpful Hints

- Create as a single document using any word processing software. Separate only at the end before uploading.
- Do not include headers or footers
- Do include a section heading as part of the text; i.e., Specific Aims, Background & Significance

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PHS 398 CHECKLIST

OMB Number: 0925-0001
Expiration Date: 09/30/2007

1. Application Type:
From SF 424 (R&R) Cover Page. The responses provided on the R&R cover page are repeated here for your reference, as you answer the questions that are specific to the PHS398.

Type of Application:
 New Renewal/Extension Renewal Continuation Revision

Project Identifier: _____

2. Change of Investigator / Change of Institution Questions

Change of principal investigator / program director

Name of former principal investigator / program director:
 First Name: _____
 Middle Name: _____
 Last Name: _____
 Title: _____

Change of Grantee Institution

Name of former institution: _____

3. Inventions and Patents (For renewal applications only)

Inventions and Patents: Yes No

If the answer is "Yes" then please answer the following:

Previously Reported: Yes No

**PHS398
Checklist
Page 1**

4. Program Income

In program income anticipated during the periods for which the grant support is requested?

Yes No

If you checked "yes" above indicating that program income is anticipated, then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

Budget Period Anticipated Amount (\$): Source(s)

5. Assurances/Certifications (see instructions)


In response to the assurance/certification section 18 on the SF424 (R&R) form, the authorized organizational representative agrees to comply with the following policies, assurances and/or certifications when applicable. Description of individual assurance/certification can be found at <http://www.fda.gov/oc/ohrt/assurances.htm>

Human Subjects: "Research Using Human Subjects: Stem Cells," "Research on Transplantation of Human Fetal Tissue," "Human and Minority Inclusion Policy," "Inclusion of Children Policy," "Vulnerable Adults," "Department and Supervision," "Drug-Free Workplace Requirements for NIH Staff," "Sexual Harassment Policy," "Confidentiality Policy," "Confidentiality on Patient Data," "Research Misconduct," "Data Rights Policy NIH 441 or NIH 565," "Non-Competing Individuals," "Phase 1/1B/1C/1D or NIH 555," "Site Documentation," "Phase 1/1B/1C/1D or NIH 565," "Site Documentation (Site 1/1B/1C/1D or NIH 565)," "Research and Data and Human Subject Transfer," "Research," "Financial Conflict of Interest except Phase 1 (NIH/OT17)," "Whistleblower Research," "Sole Agent," "Service Free Workplace," "NIH Only," "Confidentiality of Research Institution Information"

Available to search [publicly](#), when applicable, provide an explanation and effort below.


Explanation: _____

**PHS398
Checklist
Page 2**



Component: PHS 398 Checklist

- Captures additional information currently captured in the PHS398 Checklist
 - Change of PI
 - Change of Grantee Institution
 - Inventions & Patents
 - Program Income
 - PDF Text Upload for and Assurances/Certifications explanation



What will a completed application look like?

- After submission, the eRA system will:
 - Assemble the grant image
 - Generate a Table of Contents
 - Include headers (PI name) & footers (page numbers) on all pages
- "eRA Assembly of Grant Application" is found at: <http://grants.nih.gov/grants/funding/424/index.htm>
 (A document providing a sample Table of Contents & a chart cross-referencing the location in the forms components for each piece of the grant image)

424 R&R and PHS-398 Specific Table of Contents

	<i>Page Numbers</i>
SF 424 R&R Face Page	1
Table of Contents	3
Research & Related Project/Performance Site Location(s)	_____
Additional Locations	_____
Research & Related Other Project Information	_____
Project Summary/Abstract (Description)	_____
Public Health Relevance Statement	_____
Bibliography & References Cited	_____
Facilities & Other Resources	_____
Equipment	_____
Research & Related Senior/Key Person	_____
Biographical Sketches for each listed Senior/Key Person	_____
Additional Senior/Key Person Profiles	_____
Additional Biographical Sketches	_____
Research & Related Budget – Year 1	_____
Research & Related Budget – Year 2	_____
Research & Related Budget – Year 3	_____
Research & Related Budget – Year 4	_____
Research & Related Budget – Year 5	_____
Research & Related Budget – Cumulative Budget	_____
Research & Related Consortium Budget	_____

SBIR/STTR Information	_____
Research & Development Outside the U.S.	_____
Commercialization Plan	_____
Prior SBIR Phase II Awards	_____
PHS 398 Specific Cover Page Supplement	_____
PHS 398 Specific Modular Budget	_____
Personnel Justification	_____
Consortium Justification	_____
Additional Narrative Justification	_____
PHS 398 Specific Research Plan	_____
Introduction to Application	_____
Specific Aims	_____
Background and Significance	_____
Preliminary Studies/Progress Report	_____
Research Design and Methods	_____
Human Subjects Sections	_____
Protection of Human Subjects	_____
Data and Safety Monitoring Plan	_____
Inclusion of Women and Minorities	_____
Targeted/Planned Enrollment Table	_____
Inclusion of Children	_____
Vertebrate Animals	_____
Consortium/Contractual Arrangements	_____
Resource Sharing Plan	_____
Letters of Support	_____
PHS 398 Checklist	_____
PHS 398 Specific Assurances/Certification Explanation	_____
Appendix	_____

New Terminology: Type of Application

NIH Term	(R&R) Term
New (T-1)	New
Competing Continuation (T-2)	Renewal
Revision or Amendment	Resubmission
Competing Supplement	Revision

R&R Type of Application also include "Continuation". This is equivalent to our Progress Report or T-5. NIH will not use the R&R for progress reports. 85

New Terminology

NIH Term	(R&R) Term
PA and/or RFA	Funding Opportunity Announcement (FOA) —general term for all PAs and RFAs
PI	PD/PI: Combined term
Authorized Organizational Official (AOO) or Signing Official (SO)	Authorized Organizational Representative (AOR)
Other Support	Current & Pending Support

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New Terminology

NIH Term	(R&R) Term
Literature Cited (Part G. of 398 Research Plan)	"Bibliography & References Cited" in R&R Other Project Information Component
Consortium Budget	Subaward Budget

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Advice from Experience

Read and follow all application instructions!

- o Failure to follow instructions has resulted in applicants having to submit corrected applications.
- o Two most common problems with applications to date:
 - There are application fields not marked as mandatory on the federal-wide form but that are required by NIH
 - Example: **The credential field of the R&R Senior/Key Person Profile component MUST contain the PI's assigned eRA Commons User ID for NIH to process the application submission**
 - All non-Pure Edge attachments **MUST** be in PDF format
 - NIH systems cannot accommodate other types of documents

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Advice from Experience

- o Tips for creating PDF files
 - Use no special characters in file names
 - Do not write protect the PDF file
 - Turn electronic signature option "off" (in Adobe it is in security settings)

For more information see Tips and Tricks at http://era.nih.gov/ElectronicReceipt/tips_tools.htm

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Advice from Experience

- o Register now to be prepared
- o Allow time for corrections
- o See it through to verification in eRA Commons to complete the application process
- o When seeking support, be prepared to provide identifying information for your application and organization

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Next Steps: NIH

Areas we are addressing:

- Help desk staffing
- Resolving technical system issues
- Better educating NIH staff
- Reviewing business rules (validations) enforced by the system
- Outreach to the applicant community
- Re-evaluation of verification process
- Examining Registration Process for Improvements

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Next Steps: Grantees

- Review eSubmission website:
<http://era.nih.gov/ElectronicReceipt/>
- Familiarize yourself with the forms and application guide(s)
 - Application guides and sample versions of application packages are available at: <http://grants1.nih.gov/grants/funding/424/index.htm>
 - Must have PureEdge Viewer installed in order to manipulate the sample application packages. (**Check with your IT folks for permission and assistance in downloading this software**)
- Review available training resources: brochures, video library, video webcasts:
<http://era.nih.gov/ElectronicReceipt/training.htm>
- Share experiences: 1) Network at mtgs; 2) Listservs

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Next Steps: Grantees

- Determine implementation plans for *your* Institution
 - How will your internal review & approval processes change?
 - How will you share applications in progress?
 - How will you manage last minute queue at Sponsored Programs rather than airport FedEx drop box?
- Assemble a team to tackle this—faculty, administration and technical representative
- Spread the word—The SF424 (R&R) & electronic submission through Grants.gov are here!

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Electronic Submission Information:

<http://era.nih.gov/ElectronicReceipt/>

Application Guide(s), Sample Application Packages, Additional Format Pages found at:
<http://grants.nih.gov/grants/funding/424/index.htm>

SF424 (R&R) Application and Electronic Submission Information

The SF424 (R&R) will be used for electronic submission gradually replacing the PHS 398. This page provides preview versions of guides and practice application packages for preparing your application. Also, see the [Electronic Submission of Grant Applications](#) page for more information.

Preview versions of the instructions and application packages are being made available to allow you an opportunity to review and become familiar with them. We welcome comments and feedback as we finalize the guides. Send them to GSA@od.nih.gov.

NOTE: The guides are not yet final and the application packages are for practice only and not to be used to submit any applications. When a Funding Opportunity Announcement (FOA) is posted, it will have an SF424 (R&R) application package that has been populated for the specific FOA. You will use that application package to apply for the opportunity.

Sections on this Page: | [Instructions and Other Information](#) | [Application Packages](#) | [Additional Format Pages](#) | [Contacts](#) |

Instructions and Other Information	Date Posted	MS Word File	PDF File
Grants.gov Application Guide SF424 (R&R)	10/27/2005	MS Word	PDF (Coming Soon)
Grants.gov SBIR/STTR Application Guide SF424 (R&R)	11/10/2005	MS Word	PDF (Coming Soon)
vRA Assembly of the SF424(R&R) Application (An informational document describing the system-generated grant image of a SF424 (R&R) Application once submitted and received by the agency)	10/13/2005	MS Word	n/a


SAMPLE Application Packages
These Application Packages are SAMPLES only. Do not try to use these.

Training Tools:

<http://era.nih.gov/ElectronicReceipt/training.htm>

- Video library
 - Overview of NIH Transition
http://helix.od.nih.gov/oervideo/grantsgov/sf424_application/index.html
 - A Walk Through the SF424 (R&R)
http://helix.od.nih.gov/oervideo/grantsgov/A_Walk_Through_SF424/index.html
- Archive of the January 11, 2006 training session. Available in streaming video and downloadable formats


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Training Tools (cont.)

- Registration in the eRA Commons Demo
<http://era.nih.gov/virtuelschool/external/c101/GranteeRegistrationProcess.htm>
- Grants.gov's How to Complete An Application Package Demo
<http://www.grants.gov/CompleteApplication#demo>
- SF424 (R&R) application guides, sample application packages and related resources
<http://grants2.nih.gov/grants/funding/424/index.htm>

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Other Tools

- Demo Facility – By April, we plan to have an end-to-end demo facility for applicants to "practice" the entire process from finding an opportunity in Grants.gov through verifying a submitted application in the eRA Commons.
- Frequently Asked Questions
<http://era.nih.gov/ElectronicReceipt/faq.htm>
- Electronic Submission Timeline
http://era.nih.gov/ElectronicReceipt/strategy_timeline.htm
- Tips and Tools
http://era.nih.gov/ElectronicReceipt/tips_tools.htm
- Communications and Outreach resources (brochures, presentations, drop-in newsletter articles)
<http://era.nih.gov/ElectronicReceipt/communication.htm>

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Finding Help: Grants.gov Registration & Submission

If help is needed with the Grants.gov registration process or with the technical aspects of submitting through the Grants.gov system:

- Check the resources available on the Grants.gov website first (<http://grants.gov/>)
- Grants.gov help is also provided by the following office:
Grants.gov customer support
Contact Center Phone: 1-800-518-472
Business Hours M-F 7 a.m.-9 p.m. Eastern Standard Time
Email support@grants.gov

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Finding Help: eRA Commons Registration & Validations Processes

If help is needed with the eRA Commons registration process for the applicant organization and principal investigators, or with the application validation process in the eRA Commons after submission through Grants.gov, contact:

- eRA Commons help desk
Phone: 301-402-7469/866-504-9552 (Toll Free)
301-451-5939 (TTY)
Business hours M-F 7am-8pm Eastern Standard Time
Email commons@od.nih.gov
- Also visit:
eRA Commons website:
<https://commons.era.nih.gov/commons/index.jsp>
eRA website: <http://era.nih.gov>


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Finding Help: Application Preparation

- Review application instruction guide(s)
- Contact Grants Info:
Grants Info
Phone: 301-435-0714
301-451-0088 (TTY)
Email GrantsInfo@nih.gov
- All these help resources are found at:
<http://era.nih.gov/ElectronicReceipt/support.htm>

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Collecting User Feedback

- NIH has established an e-mail address to collect comments and/or suggestions from users:
NIHElectronicSubmiss@mail.nih.gov
- Share your experiences—successes and challenges
- Share specific suggestions for improvement
- What resources are most useful (*Targeted e-mails, FAQs, Tips & Tools, Commons Alerts, Training tools*)

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We're in this together.
Help spread the word!
