

#### **NIH** OFFICE OF EXTRAMURAL RESEARCH



## A Walk Through the SF424 (R&R)

NIH Office of Extramural Research
October 2008







### What is the SF424 (R&R)?

- Stands for Standard Form 424 Research and Related.
- Is actually a combination of separate forms focusing on the many aspects of a proposed grant.
- Is used government-wide to apply for all Research and Research-related grants.
  - Used by 15 different Federal agencies
  - Based on needs of all agencies, and not tailored to specific agencies, funding opportunities, or grant programs
  - Allows use of agency-specific forms and special instructions where appropriate



## Features of the SF424 (R&R)

- A complete application to NIH will include a combination of (R&R) components & PHS 398 components.
- The applicant **must** complete the application using the package attached to that particular Funding Opportunity Announcement (*Information is drawn from the specific FOA and auto-completed for use in the forms*).
- Applicants should not use any forms or sample forms from other announcements.
- Allows applicants to complete data entry in all necessary components and upload appropriate attachments.



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

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



# 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, these agency-specific components (titled PHS 398) were also developed:
  - 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
  - New PHS forms for Fellowship (F), Career Award (K) and Training (T)



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

- NIH has developed two, specific SF424 (R&R) Application Guides: 1) General Instructions; 2) General + SBIR/STTR
- Includes instructions that are imbedded in the actual forms as well as agency-specific instructions
- Agency-specific instructions denoted with the HHS Logo



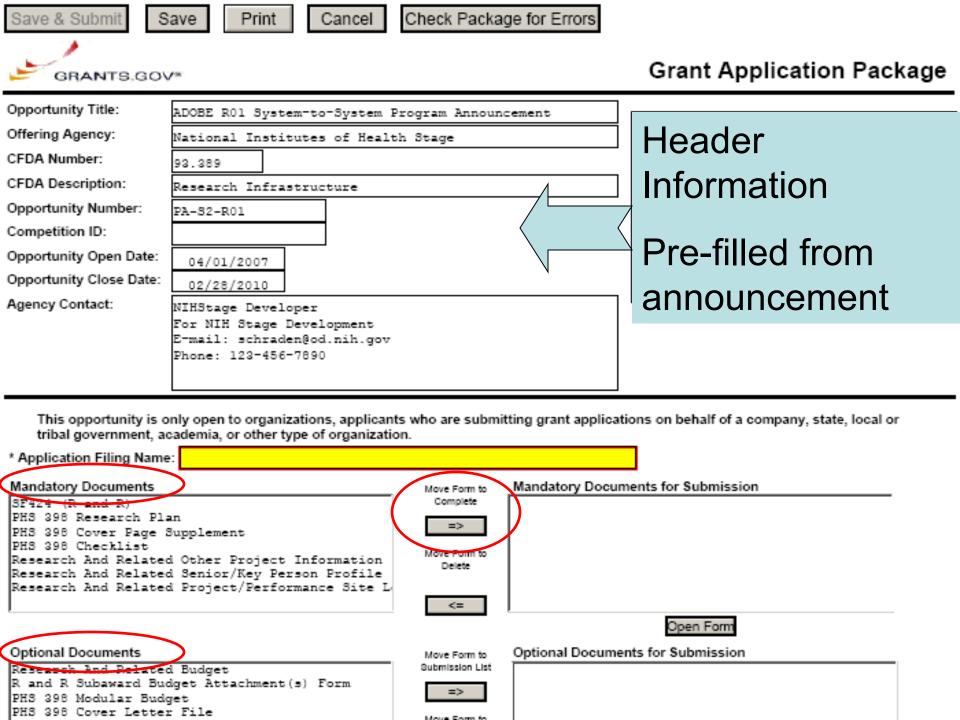
- Application Guides are split into three parts:
  - Part I: Instructions for Preparing and Submitting an Application
  - Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan
  - Part III: Policies, Assurances, Definitions



### **Accessing Application Forms**

- Find a grant opportunity in Grants.gov or the NIH Guide for Grants and Contracts.
- Click on "Apply for Grant Electronically" button in the Funding Opportunity Announcement (FOA).

  Apply for Grant Electronically
- FOA will link to Grants.gov where applications and instructions are available for download.
- In Grants.gov, use the FOA number for searching and confirming you are responding to the correct announcement.





### **Navigating Application Forms**

- The Grant Application Package Screen provides access to all appropriate forms, both components that are required (mandatory) and those that are optional.
  - Some forms that are listed as optional for Grants.gov are actually required by NIH. For example, both modular budget forms and R&R budget forms are listed as optional, though you must submit at least one (but never both).
- Click on form and move it to submission box, then open to fill in application information.
- Adobe Only Grants.gov mandatory fields are outlined in red and shaded in yellow.
  - Not all fields required by NIH are marked mandatory on the forms.

Close Form Next Print Page About					
2. DATE SUBMITTED Applicant Identifier	1				
APPLICATION FOR FEDERAL ASSISTANCE	]				
SF 424 (R&R)  3. DATE RECEIVED BY STATE State Application Identifier	l				
1. * TYPE OF SUBMISSION					
Pre-application Application 4. Pyderal Identifier	1				
Changed/Corrected Application	╄				
5. APPLICANT INFORMATION * Organizational DUNS:	Ī				
* Legal Name:	t				
Department: Division:	l				
* Street1: Street2:	l				
* City: County: * State:	l				
Province: * Country: US3  * ZIP / Postal Code:	l				
Person to be contacted on matters involving this application	t				
Prefix: *First Name: Middle Name: *Last Name: Suffic	l				
	t				
* Phone Number: Email:	l				
6. * EMPLOYER IDENTIFICATION (EIN) or (TIN): 7. * TYPE OF APPLICANT.	T				
Please select one of the following	1				
8. * TYPE OF APPLICATION: New Other (Specify):	Ī				
Small Business Organization Type   Small Business Organization Type   Women Owned   Socially and Economically Disadvantaged	l				
If Revision, of accropriate box(es).  9. * NAME OF FEDERAL AGENCY:	t				
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D. Paranaga Paralina   E. Other Inspekki	ł				
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11. * DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:	l				
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12. * AREAS AFFECTED BY PROJECT (cities; counties, states, etc.)	l				
AL REPORTED THE STATE	ł				
13. PROPOSED PROJECT:  14. CONGRESSIONAL DISTRICTS OF:  15. * Start Date * Ending Date a. * Applicant b. * Project	١				
and the second of the second o					
15. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION	t				
Prefix: *First Name: Middle Name: *Last Name: Suffix:	l				
	l				
Position/Title: * Organization Name:					
Department: Division:	l				
* Street1: Street2:	l				
*City: County: *State:					
Prevince: * ZIP / Postal Code:					
* Phone Number: * Email:					

# SF424 (R&R) Cover Component Page 1



# Notes on SF424 (R&R) Cover Component – Page 1

- Always start with the Cover Component. Information entered here pre-populates other components.
- General information about the applicant organization, contact information for the PD/PI and Authorized Organizational Representative.
- Item 1, Type of Submission
  - Pre-application—instructed not to use unless specifically noted in FOA (used by X02 grant mechanism).
  - Changed/Corrected Application— Only use when correcting an application that failed system validations. This is NOT a resubmission.
- Item 5, Organizational DUNS must match DUNS in eRA Commons profile and Grants.gov registration.
- Item 6, Include email of person to be contacted; NIH sends notifications to this address in addition to email addresses provided for PD/PI and AOR.



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

- Item 8, Type of Application-
  - New is an application submitted for the first time
  - Resubmission is 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
- Item 14, Congressional District will be moving to the Project/Performance Site Locations form in near future.



# SF424 (R&R) Cover Component - Page 2

16. ESTIMATED PROJECT FUNDING		APPLICATION SUBJECT TO REVIEW BY DER 12372 PROCESS?	STATE EXECUTIVE
a. " Total Estimated Project Funding b. " Total Federal & Non-Federal Funds c. " Estimated Program Income	b. NO	THIS PREAPPLICATION/APPLICATI AVAILABLE TO THE STATE EXECU PROCESS FOR REVIEW ON:  ATE: PROGRAM IS NOT COVERED BY E PROGRAM HAS NOT BEEN SELEC' REVIEW	TIVE ORDER 12372 .O. 12372; OR TED BY STATE FOR
18. By signing this application, I certify (1) to the situe, complete and accurate to the best of my kinesulting terms if I accept an award. I am aware criminal, civil, or administrative penalties. (U.S.  * I agree  * The list of certifications and assurances, or an internet site with	knowledge. I also provide e that any false, fictitious, . Code, Title 18, Section 1	e the required assurances * and agree to , or fraudulent statements or claims may 1001)	comply with any subject me to
19. Authorized Representative		4	
Prefix * First Name:	Middle Name:	" Last Name:	Suffix:
	<u> </u>		
* Position/Title:	" Organization:		
Department:	Division:		
* Street1:	Street2:		
* City: Co	ounty:	" State:	
Province:	"Country: USA:	* ZIP / Postal Code:	
* Phone Number: Fa	x Number:	* Email:	
* Signature of Authorized Represent	lative	^ Date Signed	
Completed on submission to Gran	its.gov	Completed on submission to	Grants.gov
20. Pre-application		Add Attachment Delete Attachme	ent View Attachment
21. Attach an additional list of Project Congressio	nai Diatricta if needed.		
Add Att	tachment Delete Atta	achment View Attachment	



RESEARCH & RELATED Project/Performance Site Location(s)	
Project/Performance Site Primary Location	
Organization Name:	
Street1:	
treet2:	
City: County:	
State: Province:	
Country: USA: UNITED STATES * ZIP / Postal Code:	
Project/Performance Site Location 1	
Organization Name:	
Street1:	
itreet2:	
City: County:	
State: Province:	
Country: USA: UNITED STATES	
	1
Next Site	
dditional Location(s)  Add Attachment  Delete Attachment  View Attachment	

- Collects data for up to eight locations
  - More than 8 locations requires a text attachment
  - Format for the attachment available at http://grants.nih.gov/grants/funding/424/index.htm

#### RESEARCH & RELATED Other Project Information

The state of the s						
1. * Are Human Subjects Involved? Yes No						
1.a If YES to Human Subjects						
Is the IRB review Pending? Yes No Other Project						
IRB Approval Date:						
Exemption Number: 1 1 2 3 14 15 16 Information						
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						
4.a. " Does this project have an actual or potential impact on the environment? Yes No						
4.b. If yes, please explain:						
4.c. If this 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?						
4.d. if yes, please explain:						
5.a. " Does this project involve activities outside the U.S. or partnership with international Collaborators?						
5.b. If yes, identify countries:						
5.c. Optional Explanation:						
6. * Project Summary/Abstract Delete Attachment View Attachment View Attachment						
7. Project Narrative Add Attachment Delete Attachment View Attachment						
8. Bibriography 8 References Cited						
9. Facilities & Other Resources Delete Attachment View Attachment						
10. Equipment Delete Attachment View Attachment						
11. Other Attachments Add Attachments Delete Attachments View Attachments						



### Other Project Information

- Items 1 and 2, Human Subject Involvement and Vertebrate Animal Use – Approval dates still provided as just-in-time information.
  - Check Yes to "Is the IRB Review Pending" and "Is the IACUC Review Pending" even if process has not begun at time of submission.
- Item 7, Project Narrative Use for the public health relevance section.
- Item 11, Other Attachments Only complete this item when requested in the FOA.

PROFILE - Project Director/Principal Investigator						
Prefix "First Name Middle	Name "Last Name Suffix					
Position/Title:	Department:					
Organization Name:	Division:					
* Street1:	Street2:					
* C ty: County:	* State: Province:					
* Country: USA: UN * Zlp / Postal Code:						
* Phone Number	Fax Number " E-Mail					
Credential, e.g., agency login:						
* Project Role: PD/PI • O	ther Project Role Category:					
*Attach Biographical Sketch	Add Attachment Delete Attachment View Attachment					
Attach Current & Pending Support	Add Attachment   Delete Attachment   View Attachment					
	E - Senior/Key Person 1					
Prefix "First Name Middle	Name "Last Name Suffix					
Position/Title:	Department:					
Organization Name:	Division:					
" Street1:	Street2:					
" City: County:	* State: Province:					
* Country: USA: T Postal Code:						
* Phone Number	Fax Number "E-Mail					
Credential, e.g., agency login:						
* Project Role:	ther Project Role Category:					
*Attach Biographical Sketch	Add Attachment Delete Attachment View Attachment					
Attach Current & Pending Support	Add Attachment Delete Attachment View Attachment					
	Next Person					

### Senior/Key Person Profile -Expanded



## Senior/Key Person Profile

- Captures personal profile information on PD/PI, key personnel, and other significant contributors.
- eRA Commons "Credential" mandatory for all PD/PIs
- Organization Name is also required by NIH.
- Attach a Biographical sketch for each person. Format and samples are available from the SF424 (R&R) Forms Page.
- Do not attach "Current & Pending Support" unless requested in FOA. This will be requested later during the just-in-time process.
- Form captures PD/PI plus 39 others.
- Form can also be used for "Other Significant Contributors".
- Two new designations Post-Doc Scholar and Co-Investigator – will be added soon to 'Project Role.'
- The degree information will be pulled off the PHS 398 Cover Page Supplement in the near future.



# Research and Related Budget - General Notes

- R&R Budget Form is one of two "optional" forms for submitting budget information.
  - Modular budgets do not use these forms, but instead use a PHS 398 form.
  - See FOA and SF424 (R&R) Instruction Guide for information on when to use each type of budget form.
- Applicant prepares a detailed budget for every budget period.
- A detailed Cumulative budget will be systemgenerated based on the budget period data.

			RESEARCH	& RELATE	D BUDGET - SECTI	ON A & B, E	BUDGE	T PERIO	01			
* ORGANIZATIO	ONAL DUNS:									_	_	
* Budget Type:	Project	Subaward	/Consortium					R8	R	Bu	dget	t
Enter name of C	Organization:											
Delete Entry	* Start Date	C	* End Date:	Bud	dget Period 1			Se	ct	ions	3 A 8	& B
A. Senior/Key Per	Son						60			* Requested		
Prefix * Fir	st Name Mi	ddle Name	* Last Name	Suffix	* Project Role	Base Salary (	Ca Mon	the Months		Salary (\$)	* Fringe Benefits (\$)	* Funds Requested (\$)
1.					PD/PI							
2.			1				- -	-				
3. <b>▼</b>			][ ][	<u> </u>			뉴					
5.							╬	╬		$\vdash$		
6.				<u> </u>			$\exists \vdash$	╗				
7.				_			<b>\</b> _					
8.												
<ol><li>Total Funda req</li></ol>	juested for all S	enior Key Perso	ons in the attached	l file								
						,				Total Sen	lor/Key Person	
Additional Seni	lor Key Person	3:			Add Attachment	Delete At	achment	View	Attachmer	nt		
B. Other Person * Number o							Cal	. Acad.	Sum.	* Requested	* Fringe	
Personnel				Project Role				hs Months		Salary (\$)	Benefits (\$)	* Funds Requested (\$)
	Post Docto	oral Associates										
	Graduate :	Students										
		uate Students										
	Secretaria	l/Clerical							lacksquare			
							╬	╬	-		<u> </u>	-
							╬	╬	╁			
	Total Num	ber Other Person	nei								Other Personne	
							Tota	al Salary.	Wages	and Fringe E	Benefits (A+B	3)



### R&R Budget Sections A & B

#### Personnel separated into 2 sections:

- A. Senior/Key Person
  - Allows 8 as separate named individuals
  - Provide info on additional Senior/Key persons in a text attachment
  - Provide time in "person-months" units, not percent effort
  - PD/PI field must be filled-in
- B. Other Personnel
  - Postdocs, Grad Students, Undergrads: Only the number of personnel is required (not specific names or responsibilities)
  - Provide more detail in Budget Justification
  - "Base Salary" can be left blank when applying but NIH will require the information before the grant is awarded

ORGANIZATIONAL DUNS:  Budget Type: Project Subaward/Consortium	
enter name of Organization:  Delete Entry * Start Date: * End Date: Budget Perio	R&R Budget
C. Equipment Description	Sections C - E
List items and dollar amount for each item exceeding \$5,000	* Funds Requested (\$)
1. Equipment item	- Funds Requested (\$)
2.	
3.	
4.	
5.	
6.	
1.	
8.	
9.	
11. Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: Add A	ttachment Delete Attachment View Attachment
D. Travel	Funds Requested (\$)
Domestic Travel Costs ( Incl. Canada, Mexico and U.S. Possessions)	
Foreign Travel Costs     Total Travel Cost	
Total Havel Cost	·
E. Participant/Trainee Support Costs	Funds Requested (\$)
Tultion/Fees/Health Insurance	
2. Stipends	
3. Travel	
Subsistence	
Other     Number of Participants/Trainees	
manipul of Participanter Frances Total Participante Frances aupport Costs	·



### R&R Budget Sections C - E

- Item C, Equipment allows itemization of up to 10 pieces of equipment. If more, include total dollars in line 11 and provide details in the attachment.
- Item D, Travel separates Domestic and Foreign travel, but NIH continues to award as a single category.
- Item E, Participant/Trainee Support Costs not used unless requested in FOA.

RESEARCH & REL	ATED BUDG	ET - SECTION I	F-K, BUDGET PERIOD 1
ORGANIZATIONAL DUNS:		1	
* Budget Type: Project Subaward/C	ansortium	•	
Enter name of Organization:		٦	
Delete Entry Start Date: * En	nd Date:	Budget Perl	od 1
F. Other Direct Costs			Funds Requested (\$)
Materials and Supplies			
Publication Costs			
Consultant Services			
4. ADD/Computer Services			
Subawards/Consortium/Contractual Costs			
6. Equipment or Facility Rental/User Fees			
7. Alterations and Renovations			
8.			
9.			
10.			
	Total Oth	er Direct Costs	ş
G. Direct Costs			Funds Requested (\$)
C. 211011 COSE	Total Direct (	Costs (A thru F	
	Total Direct	sosis (Francis	
II to discol Contr			
H. Indirect Costs Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	* Funds Requested (\$)
	Nate (26)	Dase (4)	Fullus Requesteu (a)
1.	<u> </u>		
2.	<u> </u>		
3.	<u> </u>		
4.			
	lota	I Indirect Costs	
Cognizant Federal Agency			
(Agency Name, POC Name, and POC Phone Number)			
I. Total Direct and Indirect Costs			Funds Requested (\$)
Total Direct and Indirect Inc	stitutional Costs	(G + H)	
J. Fee			Funds Requested (\$)
***			
K. * Budget Justification	and the h	Add Att	achment Delete Attachm

#### R&R Budget **Sections F - K**

- Include tuition remission in Item F, Other Direct Costs.
- •Item F(5), Consortium Costs is not auto-populated.
- Next Period Button at top of page not available until all required data fields in this component are completed, including the budget justification.

#### 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 PDF 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	View Attachment
2) Please attach Attachment 2	Add Attachment	Delete Attachment	View Attachment
3) Please attach Attachment 3	Add Attachment	Delete Attachment	View Attachment
4) Please attach Attachment 4	Add Attachment	Delete Attachment	View Attachment
5) Please attach Attachment 5	Add Attachment	Delete Attachment	View Attachment
6) Please attach Attachment 6	Add Attachment	Delete Attachment	View Attachment
7) Please attach Attachment 7	Add Attachment	Delete Attachment	View Attachment
8) Please attach Attachment 8	Add Attachment	Delete Attachment	View Attachment
9) Please attach Attachment 9	Add Attachment	Delete Attachment	View Attachment
10) Please attach Attachment 10	Add Attachment	Delete Attachment	View Attachment



# R&R Subaward Budget Attachment Form

- Used for detailed budget from all consortium grantees.
- 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.
- Consortium grantee(s) must have a version of Adobe Reader that is compatible with Grants.gov's forms.
- Allows up to 10 separate budget attachments.
  - Provide one budget for each consortium grantee
  - If more than 10 consortium partners, include details for 11 and above as PDF documents in budget justification.

#### **SBIR/STTR Information**

OMB Number: 0925-0001

Expiration Date: 09/30/2007

* Program	Type (select only one)
SBIR	STTR
Both (S	See agency-specific instructions to determine whether a particular agency allows a single submission for both SBIR and STTR)
* SBIR/STT	TR Type (select only one)
Phase I	Phase II
Fast-Trac	ck (See agency-specific instructions to determine whether a particular agency participates in Fast-Track)
Qu	uestions 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?
Yes	* 2. Does this application include subcontracts with Federal laboratories or any other Federal Government agencies?
No	* If yes, insert the names of the Federal laboratories/agencies:
Yes No	* 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
Yes	* 4. Will all research and development on the project be performed in its entirety in the United States?
No	If no, provide an explanation in an attached file.
	* Explanation: Add Attachment Delete Attachment View Attachment
Yes	* 5. Has the applicant and/or Program Director/Principal Investigator submitted proposals for essentially equivalent work under other
No	Federal program solicitations or received other Federal awards for essentially equivalent work?
	* If yes, insert the names of the other Federal agencies:
Yes	* 6. Disclosure Permission Statement: If this application does not result in an award, is the Government permitted to disclose the title of
No	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 contacting you for further information (e.g., possible collaborations, investment)?
	7. Commercialization Plan: If you are submitting a Phase II or Phase I/Phase II Fast-Track Application, include a Commercialization
	Plan in accordance with the agency announcement and/or agency-specific instructions.
	* Attach File:   Add Attachment   Delete Attachment   View Attachment

# SBIR/STTR Information

### Page 1



# SBIR/STTR Information (Pages 1 and 2)

- Item 1, Eligibility Applicants must meet SBIR/STTR eligibility requirements at time of award, not time of application.
- Item 6, Disclosure Permission Statement
  - Allows NIH to share contact information and project title to outside partners for possible collaborations or investments.
- Item 7, Commercialization Plan Include as a PDF attachment.



# SBIR/STTR Information (Page 2)

	SBIR/STTR Information					
	ecific Question		ou are submitting ONLV an STTP	application leave ou	unctions 8 and 0 blank and proceed to	
question 1		у to зык аррисацопз. 11 ус	ou are submitting <u>ONL1</u> an STTR	аррисацоп, теаче qu	estions 8 and 9 blank and proceed to	
Yes No	accordance with according instructions using the attachment					
	* Attach File:		Add Attachment	Delete Attachment	View Attachment	
Yes No	o. This die Tojest Director Theological Table Heritage Printerly employment that the Shake at the time of artists.					
CTTD C	acific Questio					
·	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	* 10. Please indic	ate whether the answer to BC	OTH of the following questions is TF	RUE:		
No	(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?					
Yes No	institution named in the application perform at least 30% of the work?					



# Agency-specific Components (a.k.a. PHS 398 Components)

- Form pages used in addition to standard SF424, and included in the NIH form set:
  - 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
  - New PHS forms for Fellowship (F), Career Award (K) and Training (T)
- Allows NIH to collect information not provided by other research agencies.



### PHS 398 Cover Letter

Close Form		Print Page About
	PHS 398 Cover Letter	
		OMB Number: 0925-0001 Expiration Date: 9/30/2007
*Mandatory Cover Letter Filename:		
Add Cover Letter File	Delete Cover Letter File	View Cover Letter File

 A suggested format for cover letters is described in SF424 (R&R) Application Guides.

Project Director / Principal Investigator (PD/PI)
Prefic * First Name:
Middle Name:
* Last Name: Suffic:
*New Investigator? No Yes
Degrees:
2. Haman Subjects
Clinical Trial?
* Agency-Defined Phase III Clinical Trial? No Yes
3. Applicant Organization Contact
Person to be contacted on matters involving this application  Prefix * First Name:
Middle Name:
* Last Nerre: Suffic:
* Phone Number:
Email:
* Title:
* Street1:
Street: *City:
County:
Province:
*Country: USA: UNITED STATES *Zip/Postal Code:

# PHS 398 Cover Page Supplement Page 1

4. Human Embryonic Stem Cells		
* Does the proposed project involve human embryonic stem cells?		
If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://stemcells.nih.gov/registry/index.asp. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:		
Cell Line(s):  Specific stem cell line cannot be referenced at this time. One from the registry will be used.		

# PHS 398 Cover Page Supplement Page 2



### PHS 398 Cover Page Supplement Pages 1 and 2

- Companion forms to the (R&R) Cover Component providing NIH with additional needed information.
- For the PD/PI, includes New Investigator code & Degree fields.
- Includes Clinical Trial and Agency-Defined Phase III Clinical Trial indicators.
- For the Business Official Contact, includes complete contact information (title & mailing address missing from section 5 of the R&R Cover).
- Page 2 includes Human Embryonic Stem Cells item.

Budget Period: 1		
Reset Entries Start Date:	End Date:	
A. Direct Costs	* Funds Requested (3)	
	Direct Cost less Consortium F&A	
	Consortium F&A * Total Direct Costs	
B. Indirect Costs	Indirect Cost Interect Cost	
Indirect Cost Type	Rate (%) Base (\$) * Funds Requested (\$)	
1.		
2.		
3.		
4.		
Cognizant Agency (Agency Name, POC Name and Phone Number)		
Indirect Cost Rate Agreement Date	Total Indirect Costs	
C. Total Direct and Indirect Costs (A + B)	Funds Requested (S)	
Budget Period: 2		
Reset Entries Start Date:	End Date:	
A. Direct Costs	* Funds Requested (5)	
	* Direct Cost less Consortium F&A  Consortium F&A	
	* Total Direct Costs	
B. Indirect Costs		
Indirect Cost Type	Indirect Cost Indirect Cost Rate (%) Base (\$) *Funds Requested (\$)	
1.		
2.		
3.		
4.		
Cognizant Agency (Agency Name, POC Name and Phone Number)		
Indirect Cost Rate Agreement Date	Total Indirect Costs	
C. Total Direct and Indirect Costs (A + B)	Funds Requested (S)	

## PHS 398 Modular Budget



### PHS 398 Modular Budget

- Alternative to the R&R Budget form that doesn't require detailed categorical information.
- Available to certain applicants requesting \$250,000 or less in Direct Costs per year.
- Applicants must request total direct costs in "modules" of \$25,000.
- Direct costs are separated from consortium F&A costs since these are not included in the \$250K limit.
- Cumulative Budget is system-generated.
- Form requires Budget Justification PDF text attachments for Personnel, Consortium and Other.

1. Application Type:				
From SF 424 (R&R) Cover Page and PHS39 are repeated for your reference, as you attac			rding the type of applic	ation being submitte
"Type of Application:				
New Resubmission Ren	ewal Continuation Revision	]		
2. Research Plan Attachments:				
Please attach applicable sections of the re-	search plan, below.			
1. Introduction to Application		Add Attachment	Delete Attachment	View Attachment
(for RESUBMISSION or REVISION only)				
2. Specific Aims		Add Attachment	Delete Attachment	View Attachment
3. Background and Significance		Add Attachment	Delete Attachment	View Attachment
4. Preliminary Studies / Progress Report		Add Attachment	Delete Attachment	View Attachment
5. Research Design and Methods		Add Attachment	Delete Attachment	View Attachment
6. Inclusion Enrollment Report		Add Attachment	Delete Attachment	View Attachment
7. Progress Report Publication List		Add Attachment	Delete Attachment	View Attachment
Human Subjects Sections				
Attachments 8-11 apply only when you has Form. In this case, attachments 8-11 may Funding Opportunity Announcement to det	be required, and you are encouraged t	o consult the Applica	tion guide instructions	
8. Protection of Human Subjects		Add Attachment	Delete Attachment	View Attachment
9. Inclusion of Women and Minorities		Add Attachment	Delete Attachment	View Attachment
10. Targeted/Planned Enrollment		Add Attachment	Delete Attachment	View Attachment
11. Inclusion of Children		Add Attachment	Delete Attachment	View Attachment
Other Research Plan Sections				
12. Vertebrate Animais		Add Attachment	Delete Attachment	View Attachment
13. Select Agent Research		Add Attachment	Delete Attachment	View Attachment
14. Multiple PI Leadership Plan		Add Attachment	Delete Attachment	Vlew Attachment
15. Consortium/Contractual Arrangements		Add Attachment	Delete Attachment	View Attachment
16. Letters of Support		Add Attachment	Delete Attachment	View Attachment
17. Resource Sharing Plan(s)		Add Attachment	Delete Attachment	View Attachment
18. Appendix Add Attachments	Remove Attachments View Attachm	ents		

# PHS 398 Research Plan



## PHS 398 Research Plan

- Separate PDF attachments for each section.
- Same formatting requirements in the PHS 398 continue here—margins, page limits, etc.
- Appendix Material
  - Allows up to 10 separate attachments
  - Stored separately in the eRA grant folder, not as a part of the main application grant image
  - Accessible to appropriate NIH staff and peer reviewers



# PHS 398 Research Plan: Helpful Hints

- Create as a single document using any word processing software to track page limits. 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.



## PDF Attachment Hints

- Do not scan paper documents. Instead, produce documents with word-processing software and then convert electronically to PDF.
- Use meaningful titles for file names.
- Only use standard characters in file names:
   A-z, 0-9, Hyphen (-), Underscore (\_\_).
- Disable write-protection features.
- A zero-byte attachment is an invalid PDF.

<ol> <li>Application Type:         From SF 424 (R&amp;R) Cover Page. The responses provided on the R&amp;R cover page are repeated here for your reference, as you answer the questions that are specific to the PHS398.     </li> </ol>
* Type of Application:  New Resubmission Renewal Continuation Revision  Federal Identifier:
2. Change of Investigator / Change of Institution Questions
Change of principal investigator / program director
Name of former principal investigator / program director:  Preftx:  First Name:  Middle Name:  * Last Name:  Suffix:  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**

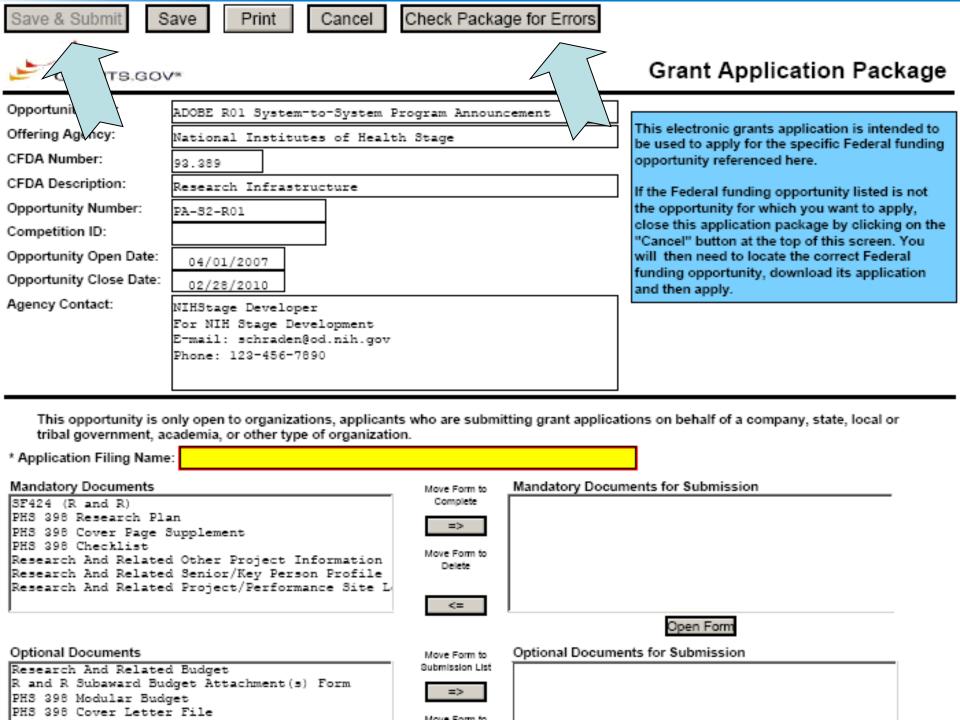
## **Checklist Page 1**

- •Captures additional information on Change of PD/PI and Change of Institution
- •Captures data on Inventions and Patents

4.* Program moome				
Is program income anticipated during the periods for which the grant support is requested?				
TYSS □HD				
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 (5) *Source(s)				
5. Assurances/Certifications (see Instructions)				
In agreeing to the assurances/certification section 18 on the SF424 (R&R) form, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the agency's application guide, when applicable. Descriptions of individual assurances/certifications are provided at: http://grants.nih.gov/grants/funding/424				
if unable to certify compliance, where applicable, provide an explanation and attach below.				
Explanation: Delete Attentionent View Attachment View Attachment				

# PHS398 Checklist Page 2

- •Captures additional information on sources of **Program Income.**
- •Allows PDF text upload if unable to certify compliance.





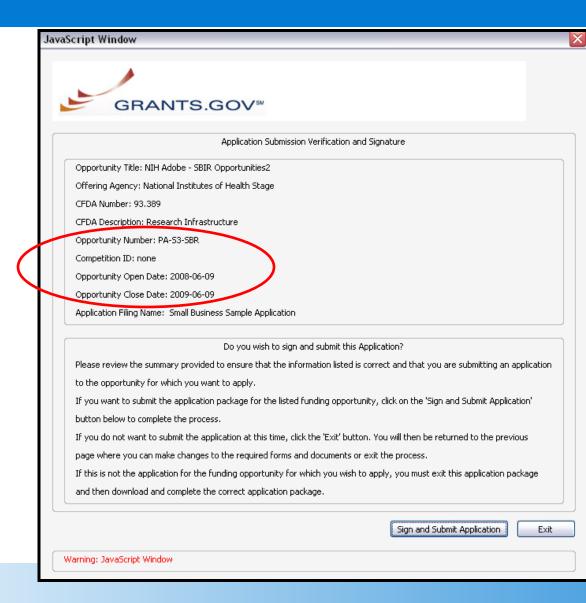
## **Application Submission**

- Save the final application document and click "Check Package for Errors" on Grant Application Package Screen. This checks for Grants.gov errors, not NIH-generated errors.
- Once all documents are properly completed and saved the "Save and Submit" button becomes active.
- Once submitted, verification and confirmation screens will appear, and applicants will receive a Grants.gov Tracking Number.



## **Application Submission**

 Check header information one last time to confirm you are submitting to correct FOA and that it has not yet closed.





## After Submission to Grants.gov

- After submission to Grants.gov, the eRA system performs agency validations.
  - Any errors must be fixed and the application resubmitted before it can be accepted for review
  - Warnings may not require fixing, but highlight potential problems/issues for applicants to consider
- If no eRA system errors identified, the eRA system will:
  - Assemble the grant image
  - Generate a Table of Contents
  - Include headers (PI name) & footers (page numbers) on all pages
- Applicants have a two business-day viewing window after successful receipt by NIH to ensure the application was submitted correctly.

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

#### Page Numbers

SF 424 R&R Face Page	<u>1</u>
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	
<b>-</b>	

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	



#### **NIH** OFFICE OF EXTRAMURAL RESEARCH



# Handy Tools and Final Thoughts





Process

Electronic Application

Transition Timeline

Avoiding Common

Frequently Asked

Questions (FAQs)

(from paper to

electronic)

Errors

Training

Resources

Finding Help

#### NIH Office of Extramural Research

#### Electronic Submission of Grant Applications

Search:



TIPS

Small Biz (PDF - 66 KB)

International (PDF - 150

Q&A (PDF - 36 KB)

Contact Info (PDF - 30

Reviewers (PDF - 52.3)

PI (PDF - 48 KB)

KB)

KB)

KB)

Advanced Search

#### http://era.nih.gov/ElectronicReceipt/

#### Home Electronic Submission

Paper No More, Use 424 (R&R)

#### Get prepared: Move to Adobe begins Dec. 2008

Most electronic submissions to NIH after Jan. 1, 2009 will require Adobe grant application forms. Visit Resources for Adobe Transition for:

- Transition schedule
- Required software
- Important to know

Prepare to Apply

Application Package

3. Prepare Application

- Frequently Asked Questions
- Resources (and more)

#### Parent Announcements

(Funding opportunities for Unsolicited or Investigator-Initiated Applications - R01, R03, R13/U13, R15, R21)

#### **Electronic Application Process**

Find Opportunity and Download

Submit Application to Grants.gov

Site Map

eRA Commons

Intranet Link (NIH Staff only)

Check Submission Status in Commons

View Process Flow

Chart (PDF - 23 KB)

6. Check Assembled Application

#### Latest Updates

eSubmission News

 Visit News and Events to get the latest eSubmission news. (Sept. 29, 2008 news

update posted)

Archive...

#### **New Postings**

- Updated SF424 (R&R) Validations (PDF - 798) posted (Oct. 10, 2008)
  - · Resources for Adobe Transition (Sept. 18, 2008) Undated SE424 (R&R).



Contact Us | Print Version Search:

Advanced Search | Site Map

Home **About Grants**  **Funding** 

Forms & Deadlines

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

#### Forms & Deadlines

#### Forms & Applications

Submission Dates / Deadlines:

Submittina Your Application:

#### Global OER Resources

Glossary & Acronyms

Frequently Used Links

Frequent Questions

#### SF424 (R&R) Application and Electronic Submission Information

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

#### PureEdge Application Instructions

One version of the application quide is currently available and is labeled as "Version 2 (to be used with applications packages indicating Version 2 or 2a)." This quide is to be used with funding opportunities using Version 2 of the SF424 (R&R) forms. These funding opportunities are clearly noted with a "VERSION-2-FORMS" or a "VERSION-2A-FORMS" in the "Competition ID" field of the forms package, and they continue to use PureEdge Viewer for submitting applications to Grants.gov.

Version 2a includes the use of the Research and Related Senior/Key Person Profile (Expanded) form in place of the previously used Senior/Key Person form. The expanded form allows the collection of structured data for up to 40 Senior/Key Persons. The expanded form appears in all application packages posted on/after November 15, 2006. This is the only change in the actual forms for packages noted as Version 2a.

#### **Adobe Application Instructions**

A separate version of the application guide to be used with the new Adobe Reader versions of the application forms is available (see NIH Guide Notice NOT-OD-08-098). These new forms are still in a limited pilot test stage and this quide should only be used when mentioned in the specific FOA. These funding opportunities are clearly noted with "ADOBE-FORMS-PILOT" in the "Competition ID" field of the forms package. See NIH Guide Notice NOT-OD-08-073 for more information on the NIH/AHRQ plan for transition from PureEdge to Adobe Reader application forms.

#### Sections on this Page:

package.

[Instructions and Other Information ] [Additional Format Pages ] [Notable Changes ] [Contacts ]

Instructions and Other Information	Date Posted	MS Word File	PDF File
PureEdge Instructions: Version 2 (including 2a) (To be used for FOAs clearly noted with "VERSION-2-FORMS" or " SF424 (R&R) forms package.)	/ERSION-2A-FOR	RMS" in "Competition	ID" field of
Application Guide SF424 (R&R) - Version 2 (for use with <b>PureEdge</b> Viewer application forms)	08/01/2008	MS Word (2.5 MB)	PDF (3 MB)
SBIR/STTR Application Guide SF424 (R&R) - Version 2 (for use with PureEdge Viewer application forms)	08/01/2008	MS Word (2.7 MB)	PDF (3.2 MB)



## Training Tools:

- Registration in the eRA Commons Demo <u>http://era.nih.gov/virtualschool/external/c101 Grant</u> <u>eeRegistrationProcess.htm</u>
- Grants.gov's How to Complete An Application Package Demo <a href="http://www.grants.gov/CompleteApplication#demo">http://www.grants.gov/CompleteApplication#demo</a>



### Other Tools

- SF424 (R&R) application guides, additional format pages and related resources <a href="http://grants.nih.gov/grants/funding/424/index.htm">http://grants.nih.gov/grants/funding/424/index.htm</a>
- Frequently Asked Questions http://era.nih.gov/ElectronicReceipt/faq.htm
- Frequently Asked Questions re: Person months <a href="http://grants.nih.gov/grants/policy/policy.htm#resources">http://grants.nih.gov/grants/policy/policy.htm#resources</a>
- Avoiding Common Errors
   http://era.nih.gov/ElectronicReceipt/avoiding\_errors.htm
- Resources for NIH Adobe Transition
   http://era.nih.gov/ElectronicReceipt/adobe\_transition.htm



## Finding Help:

- Review application instruction guide(s)
- Contact Grants Info:

**Grants Info** 

Phone: 301-435-0714

301-451-0088 (TTY)

Email GrantsInfo@nih.gov

 All other tools and resources are found at: http://era.nih.gov/ElectronicReceipt/index.htm



## Finding Help: Commons Registration & Validations

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

eRA Commons Help Desk

Web: <a href="http://ithelpdesk.nih.gov/eRA/">http://ithelpdesk.nih.gov/eRA/</a>

Toll-free: 1-866-504-9552

Phone: 301-402-7469

TTY: 301-451-5939

Hours: Mon-Fri, 7a.m. to 8 p.m. Eastern Time

Also visit:

eRA Commons website:

https://commons.era.nih.gov/commons/index.jsp



## 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, Adobe Transition Resources, Avoiding Common Errors, Training tools)



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## Questions?



