Tip:

• Some actions (e.g., Preview Application) are only available from this screen. The Return to Application action can be used to return to this screen.

Summary R	R&R Cover	Cover Page Supplement	Other Project Information	Sites	Sr/Key Person Profile	R&R Budget	R&R Subaward Budget	Modular Budget	Research Plan	Human Subjects and Clinical Trials	Assignment Request Form	
-----------	-----------	--------------------------	---------------------------------	-------	-----------------------------	------------	---------------------------	-------------------	------------------	--	-------------------------------	--

Application Information

Application Identifier:	262141
Application Project Title:	This is the official title of the proposal (Limited to 200 characters including spaces and punctuation)
PD/PI Name:	PI Last Name, PI First Name
Organization:	Louisiana State University and A&M College
Project Period:	07/01/2018 - 06/30/2020
Status:	Work in Progress Submit Application
Status Date:	2018-01-29 03:43:29.000 PM EST

FOA Information:

FOA Information:	PA-18-603
Opportunity Title:	Women and Sex/Gender Differences in Drug and Alcohol Abuse/Dependence (R01 Clinical Trial Optional)
Agency:	National Institutes of Health
CFDA Number:	
Competition ID:	FORMS-E
Competition Title:	Use for due dates on or after January 25, 2018
Opportunity Open Date:	05/05/2018
Opportunity Close Date:	05/07/2021 Closing date should be after submission or will generate Grants.gov error.
Agency Contact:	eRA Service Desk Monday to Friday 7 am to 8 pm ET http://grants.nih.gov/support/

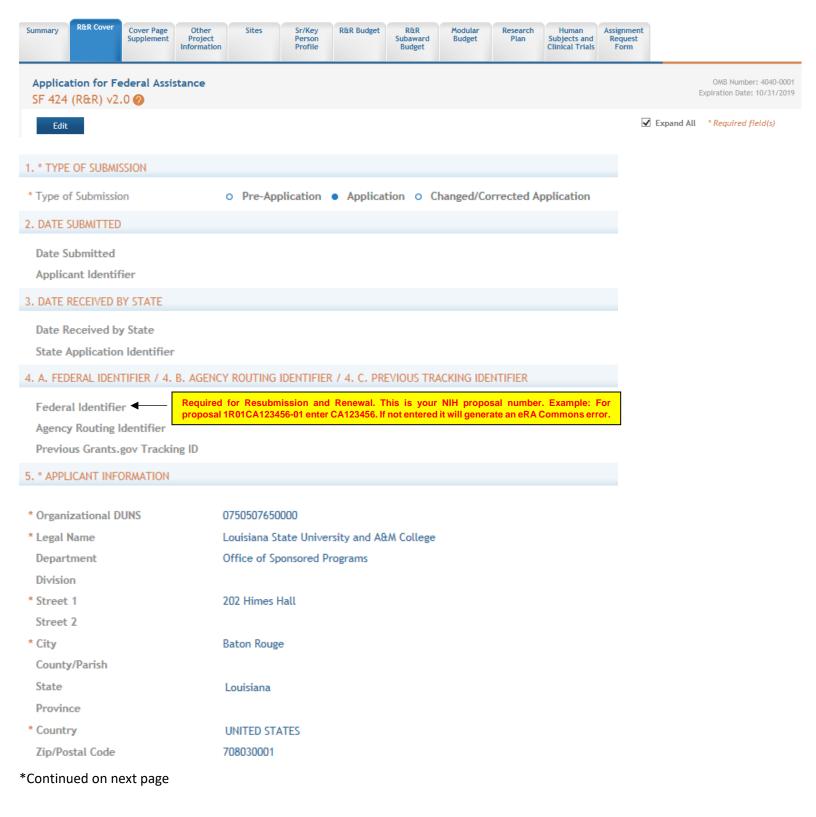
SAM Registration Expiration Date: 01/10/2019

An active SAM Registration is required to submit your application to the agency

Click for SAM Registration Details

Tips:

- Complete this form first. Some information is forward populated to other forms.
- Multi-project applications For the Overall component, complete the entire form. For other components, you will only be able to complete a subset of fields (Applicant Information, Type of Applicant optional, Descriptive Title of Applicant's Project and Proposed Project Start/End Dates). Expand All will expose fields available for data entry.



Person to be contacted on matter	rs involving this application
Prefix	Mrs.
* First Name	Darya
Middle Name	
* Last Name	Courville
Suffix	
Position/Title	Executive Director, Sponsored Programs
* Street 1	202 Himes Hall
Street 2	
* City	Baton Rouge
County/Parish	
State	Louisiana
Province	
* Country	UNITED STATES
Zip/Postal Code	708030001
* Phone Number	225-578-2760
Fax Number	225-578-2751
Email	osp@lsu.edu
6. * EMPLOYER IDENTIFICATION (EIN	I) or (TIN)
* Employer Identification	1726000848A1
5 5-	
7. * TYPE OF APPLICANT	
* Type of Applicant	H: Public/State Controlled Institution of Higher Education
Other (specify)	
Small Business Organization Type	Women Owned Socially and Economically Disadvantaged
8. * TYPE OF APPLICATION	
* • New O Resubmission O	Renewal o Continuation o Revision
If Revision, mark appropriate bo (es).	Check Resubmissions or Renewal as appropriate
A. Increase Award B. De	crease Award 🗌 C. Increase Duration 🗌 D. Decrease Duration 🗌 E. Other (specify)
* Is this application being	o Yes • No
submitted to other agencies?	
What other Agencies?	
9. * NAME OF FEDERAL AGENCY	
* Name of Federal Agency	National Institutes of Health
<i>BP</i>	
10. CATALOG OF FEDERAL DOMESTIC	ASSISTANCE NUMBER
Catalog of Federal Domestic	
Assistance Number	
Title	
11. * DESCRIPTIVE TITLE OF APPLICAT	IT'S PROJECT
* Descriptive Title of Applicant's Project	This is the official title of the proposal (Limited to 200 characters including spaces and punctuation)
12. * PROPOSED PROJECT	
* Start Date	07/01/2018 Make sure dates match the budget pages.
* Ending Date	06/30/2020
13. * CONGRESSIONAL DISTRICT OF A	PPLICANT
* Congressional District of	LA-006
Applicant	
(e.g. CA-012, outside the U.S. enter 00-000)	
enter ou-oouj	

*Continued on next page

13. * CONGRESSIONAL DISTRICT OF APPLICANT

* Congressional District of LA-006 Applicant (e.g. CA-012, outside the U.S. enter 00-000)

14. * PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

The PD/PI Contact Information on the SF 424 (R&R) Cover is populated from the PROFILE - Project Director/Principal Investigator on the Research and Related Senior/Key Person Profile (Expanded) form. If you wish to change these items, please do so on the Research and Related Senior/Key Person Profile (Expanded) form; you will not be able to edit the response here.

Prefix	Dr.		
* First Name	PI First Name		
Middle Name			
* Last Name	PI Last Name		
Suffix			
* Position/Title	PI Title		
* Organization Name	LOUISIANA STATE UNIVERSITY A&M COLLEGE		
Department			
Division			
* Street 1	PI Address		
Street 2			
* City	BATON ROUGE		
County/Parish			
* State	Louisiana		
Province			
* Country	UNITED STATES		
* Zip/Postal Code	708030001		
* Phone Number	PI Phone Number		
Fax Number	PI Fax Number		
* Email	PI_email@lsu.edu		
15. * ESTIMATED PROJECT FUNDING			
* a. Total Federal Funds Requested		400,000.00	
* b. Total Non-Federal Funds		0.00	
* c. Total Federal & Non- Federal Funds		400,000.00 <	Should match Total Direct + Indirect Costs on cumulative budget.
* d. Estimated Program		0.00	

Income

*Continued on next page

16. * IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. * Yes b. * No

This pre-application/application was made available to the State Executive Order 12372 process for review on: Date 0

Program is not covered by E.O. 12372; or o Program has not been selected by State for review .

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances* and agree to comply with any resulting terms if I accept an aware. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 218, Section 1001) ✓ * I agree

* The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.

18. SFLLL (DISCLOSURE OF LOBBYING ACTIVITIES) OR OTHER EXPLANATORY DOCUMENTATION

SFLLL (Disclosure of Lobbying View Attachment Activities) or other Explanatory Documentation

19. * AUTHORIZED REPRESENTATIVE

Prefix	Mrs.
* First Name	Darya
Middle Name	
* Last Name	Courville
Suffix	
* Position/Title	Executive Director, Sponsored Programs
* Organization	Louisiana State University and A&M College
Department	Office of Sponsored Programs
Division	
* Street 1	202 Himes Hall
Street 2	
* City	Baton Rouge
County/Parish	
* State	Louisiana
Province	
* Country	UNITED STATES
* Zip/Postal Code	708030001
* Phone Number	225-578-2760
Fax Number	225-578-2751
* Email	osp@lsu.edu
* Signature of Authorized Representative	Completed on submission to Grants.gov
* Date Signed	01/29/2018
20. PRE-APPLICATION	

Pre-application



See FOA requirements. If not applicable, answer "Program is Not Covered..." If applicable, answer "Program has not been selected ... "

View Attachment

Tip:

• Multi-project applications - In the Overall component, repeat any Human Embryonic Stem Cell lines from other components in the cell line table. For other components, enter Human Embryonic Stem Cells used for the component.



* Does the proposed project involve human embryonic stem cells? O Yes O No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: <u>http://stemcells.nih.gov/research/registry/</u>. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s): (Example: 0004)

4. Inventions and Patents Section (for Renewal applications)

* Inventions and Patents	0	Yes	0	No
If "Yes" then answer the following:				
* Previously Reported	0	Yes	0	No

5. Change of Investigator/Change of Institution Section

Change of Project Director/Principal Investigator Name of former Project Director/Principal Investigator Prefix

* First Name

Middle Name

* Last Name Suffix

Change of Grantee Institution

* Name of former Institution

Tips:

For Multi Project Applications:

- Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions for non-Overall components.
- Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question for non-Overall components.
- Project Narrative: Required for Overall component. Check FOA instructions for all other components.

Summary I	R&R Cover	Cover Page Supplement	Other Project Information	Sites	Sr/Key Person Profile	R&R Budget	R&R Subaward Budget	Modular Budget	Research Plan	Human Subjects and Clinical Trials	Assignment Request Form			
Research R&R Oth			Project Info 4 🕜	rmation									OMB Numbe Expiration Date	er: 4040-0001 : 10/31/2019
Edit													* Required ;	field(s)
	uman Subje					•	Yes O No							
	YES to Hum the project	-	rom Federal ı	egulations?		0	Yes • No	•	If ex	cemption is "y	ves" must o	check exem	nption # box (5
lf	yes, check	the appro	priate exemp	tion number.			1 🗌 2 🔲 🛛	3 4	5 6	7 8				
lf	no, is the l	RB review	Pending?			•	Yes O No	<	If answer	is "No" then	you must	enter IRB	approval	
IR	RB Approval	Date								Human Subje enter Humar				
Hu	uman Subje	ects Assura	nce Number			000	03892	←		will generate				
2. * Are Ve	ertebrate A	nimals Use	d?			•	Yes o No							
	YES to Vert													
	the IACUC		nding?			•	Yes O No							
	CUC Appro		N			D1/	00272	Will o	ionorato oP	A Commons e	error if #2 is	checked ('Ves" and thi	e ie blank
			ice Number			Die	-00372		jenerale ek	A COMMONS E	1101 II #2 I	Scheckeu	res anu un	
applic	ation?	-	ormation incl			0	Yes o No	lf "Y	es", refer to	instructions	on how to l	abel propri	ietary inform	ation
posi	itive or neg	ative - on t	actual or pot he environme	ential impact ent?	-	0	Yes O No							
	f yes, pleas	-												
ei	nvironment	t, has an ex tal assessm	ent (EA) or en	tial impact on n authorized o nvironmental i	or an	0	Yes O No							
4.d. lf	f yes, please	e explain:												
be des	research po signated, as f yes, please	a historic	-	ted, or eligible	e to	0	Yes O No							
States		ships with	international	le of the Unite collaborators		0	Yes O No							
6.b. 0)ptional Exp	lanation:												
7. * Project	Summary/A	bstract	Project_Sum	nary.pdf 🗲				. If exceed	d it will ge	nerate an eR.	A Vie	ew Attachme	ent	
8. * Project	Narrative		Project_Narra	ative.pdf		nmons error						ew Attachme	ent	
9. Bibliograp Cited	phy & Refere	ences	Literature_Ci	ted.pdf		nited to 2-3 nmons error		If exceed	it will ger	erate an eR		ew Attachme	ent	
10. Facilitie	es & Other R	esources	Facilities_Res	ources.pdf							Vie	ew Attachme	ent	
11. Equipme	ent		Equipment_A	vailable.pdf							Vie	ew Attachme	ent	
12. Other At	ttachments													
					Atta	ichment File N	ame						View Attachn	nent
Nothing found	id to display.		n	II attachment lore) between &) in file name	words or	characters.	Avoid use of	f ampersar						

All editable fields marked with $\square^*\square$ must be entered in order to Save this form. Please gather these data before beginning your data entry.

Summary	R&R Cover	Cover Page Supplement	Other Project Information	Sites	Sr/Key Person Profile	R&R Budget	R&R Subaward Budget	Modular Budget	Research Plan	Human Subjects and Clinical Trials	
Assignment Request Form											
Project/Perfo	ormance Site Lo	cations Summary	L								
-	:/Performa manceSite	nce Site Lo v2.0 🕜	ocation(s)						Exp	OMB Number: 4040 Diration Date: 10/31	
Edit										* Required field(s)
organiza Projec	ation V	Do not chee nance Site	s an individual, sk, it will genera Primary L	te eRA Commo		mpany, state,	ocal or tribal į	government,	academia, or	other type of	
Organiza	tion Name	Louisian	a State Univers	sity and A&M (College						
DUNS Nu (e.g. 123 1234567	3456789 or	0750507	650000	Gener	rates eRA Co	mmons error if r	ot entered				
* Street 1		PI addre	955								
Street 2											
* City		Baton R	ouge								
County/P	Parish										
State		Louisiar	าล			~					
Province	i i										
* Country		UNITED	STATES			~					
Zip/Posta	al Code	7080300	01								
Congress (e.g. CA-	Performance S sional District 012, outside er 00-000)	a second second									

Project/Performance PerformanceSite v		OMB Number: 4040-0010 Expiration Date: 10/31/2019
Edit		* Required field(s)
organization	plication as an individual, and not on behalf of a company, state, local or tribal government, academ Do not check, it will generate eRA Commons error Ince Site Location 1	nia, or other type of
Populate from R&R Co	ver	
Organization Name	Subrecipient organization name	
DUNS Number (e.g. 123456789 or 1234567891234)	000000000000 Enter Subrecipient's DUNS #	
* Street 1	Subrecipient address	
Street 2		
* City	Subrecipient city	
County/Parish	1	
State	Louisiana	
Province		
* Country	UNITED STATES	
Zip/Postal Code	00000000	
Project/Performance Site Congressional District (e.g. CA-012, outside the U.S. enter 00-000)	LA-006 Enter Subrecipient's congressional district	

Tips:

For Multi Project Applications:

- For the Overall component, enter the Primary Site only.
- For other components, list all performance sites that are part of the component.

Summary I	R&R Cover	Cover Page Supplement	Other Project Information	Sites	Sr/Key Person Profile	R&R Budget	R&R Subaward Budget	Modular Budget	Research Plan	Human Subjects and Clinical Trials	Assignment Request Form		
Project/Perfor Primary		Locations Sum ance Site	Exam			ee after yo above and s							
		Organization	n Name			DUNS			Address			Act	ion
Louisiana	a State Unive	ersity and A&N	\ College		0750507	650000		dress Rouge, LA 708 D STATES	8030001			Edit	View
Project/	Perform	ance Site	Location(s	Add Site									
													One item found
Entry #		Organizati	on Name		DUI	45		Addre	ess			Action	
1	Subreci	pient organiza	tion name	00000000	00000		Subreci	pient address pient city, LA (STATES	00000000		Edit	Remove Vie	w

All editable fields marked with a * must be entered in order to Save this form. Please gather these data before beginning your data entry.

ummary	R&R Cover	Cover Page Supplement	Other Project Information	Sites	Sr/Key Person Profile	R&R Budget	R&R Subaward Budget	Modular Budget	Research Plan	Human Subjects and Clinical Trials
signment Request Form										
Key Persor	n Summary									
(Expan			Key Person	Profile					Exp	OMB Number: 4040-000 piration Date: 10/31/201
			1 VZ.0 🌍							
Edit			1 v2.0 🌍							* Required field(s)
			or/Principa	al Investig	gator		<u> </u>	Click this aft	er entering us	* Required field(s) ername to populate fiel
PROFI		ect Directo	or/Principa		_	e fields from Cre			er entering use	
PROFI Credent: login Prefix	LE - Proje	ect Directo	or/Principa ame		_		edentials		er entering us	
PROFI Credent login Prefix	I LE - Proje ial, e.g., agen me	ect Directo cy Pluserna Dr.	or/Principa ame		_				er entering us	
PROFI Credent login Prefix First Nat	ILE - Proje ial, e.g., agen me łame	ect Directo cy Pluserna Dr.	or/Principa ame Name		_				er entering us	
PROFI Credent login Prefix First Nat	ILE - Proje ial, e.g., agen me łame	ect Directo cy Plusern Dr. Pl First Pl Last	or/Principa ame Name]	_				er entering us	
PROFI Credent login Prefix * First Nat Middle N	I <mark>LE - Proje</mark> ial, e.g., agen me łame ne	ect Directo cy Plusern Dr. Pl First Pl Last	name]	_				er entering us	

Organization Name	LOUISIANA STATE UNIVERSITY A&M COLL	LEGE	
Division			
* Street 1	PI Address		
Street 2			
* City	BATON ROUGE		
County/Parish			
State	Louisiana	\checkmark	
Province			
* Country	UNITED STATES	~	
* Zip/Postal Code	708030001		
* Phone Number	PI Phone Number		
Fax Number	PI Fax Number		
* E-Mail	Pl_email@lsu.edu		
* Project Role	PD/PI		
Other Project Role Category			
Degree Type			
Degree Year		l	If the degree does not match the PI's eRA Commons personal profile, this may generate eRA Commons warning.
Attach Biographical Sketch	Bio_Sketch.pdf	Replace Attachment De	elete Attachment View Attachment
Attach Current & Pending Support		Add Attachment Delete	Attachment View Attachment

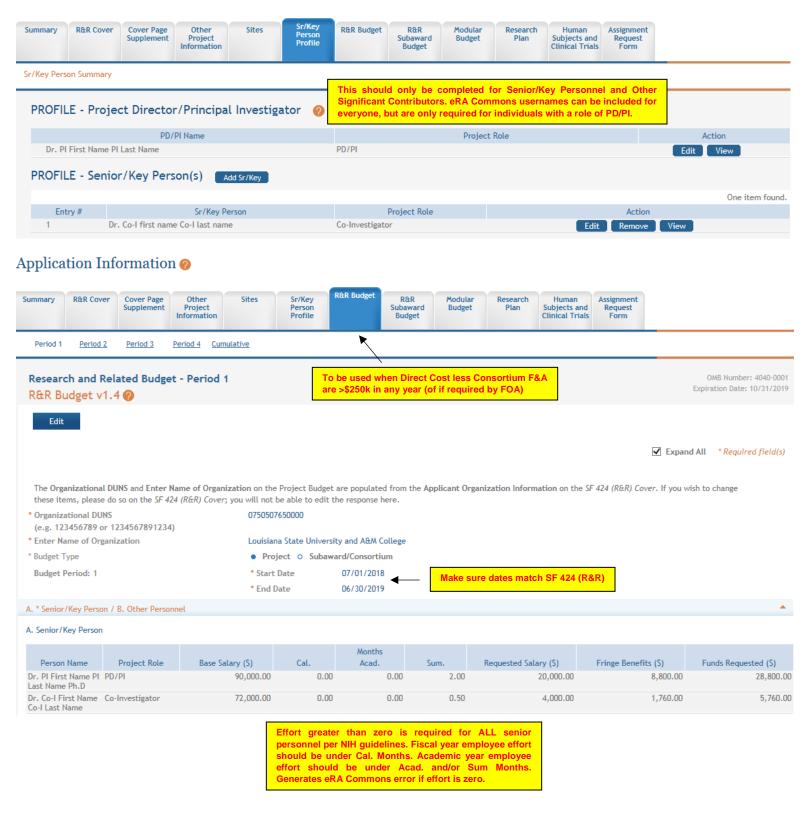
PROFILE - Senior/Key Person 1

Credential, e.g., agency	Populate fields from Credentials
login	
Prefix	Dr.
* First Name	Co-I first name
Middle Name	
* Last Name	Co-I last name
Suffix	Select Suffix 🖌
Position/Title	Co-I title
Department	
Organization Name	LOUISIANA STATE UNIVERSITY A&M COLLEGE
Division	
* Street 1	Co-I address
Street 2	
* City	Baton Rouge
County/Parish	
State	Louisiana
Province	
* Country	UNITED STATES
* Zip/Postal Code	708030001 Project Role: Other (Specify) and Other Project Role Category:
* Phone Number	Co-I phone number Other Significant Contributor OSC should be listed last after all Senior/Key Personnel.
Fax Number	Co-I fax number The role of "Co-PI/Co-PD" is not appropriate for multi-PI
* E-Mail	submissions. Will generate eRA Commons warning. For multi- PI submission, use role of "PD/PI" and include eRA Commons
* Project Role	Co-Investigator
Other Project Role Category Degree Type	certifications in SPS for LSU PI's.
Degree Year	Bio Sketch is limited to 5 pages. If exceed it will generate an eRA Commons error
Attach Biographical Sketch	Bio_Sketch.pdf Replace Attachment Delete Attachment View Attachment
Attach Current & Pending Support	Add Attachment Delete Attachment View Attachment
	Save and Keep Lock Save and Release Lock Save and Add Cancel and Release Lock
	Sare and help both Sare and help both

Tips:

For Multi Project Applications:

- In the Overall component, only enter the PD/PI and any multi-PD/PIs for the entire application and use the PD/PI role for each.
- · For other components, enter all Sr/Key for that component and use roles other than PD/PI.
- · Each Sr/Key person gets one biosketch covering their involvement for the entire application. It does not matter which component is chosen to include the single biosketch.
- A system-generated Summary of Sr/Key persons and their biosketches will appear with the Overall component when the application is assembled. Biosketches will not be included in component previews.



Additional Senior/Key Persons

Total Funds requested for all Senior/Key Persons in the attached file $~\,$ $\,$

34,560.00

\$

View Attachment

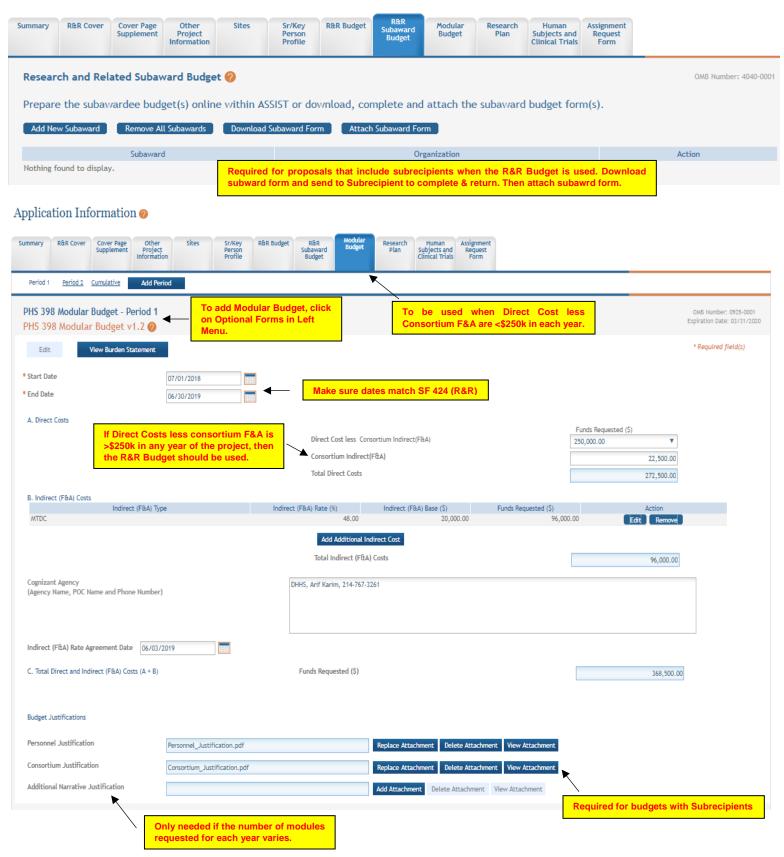
B. Other Personnel

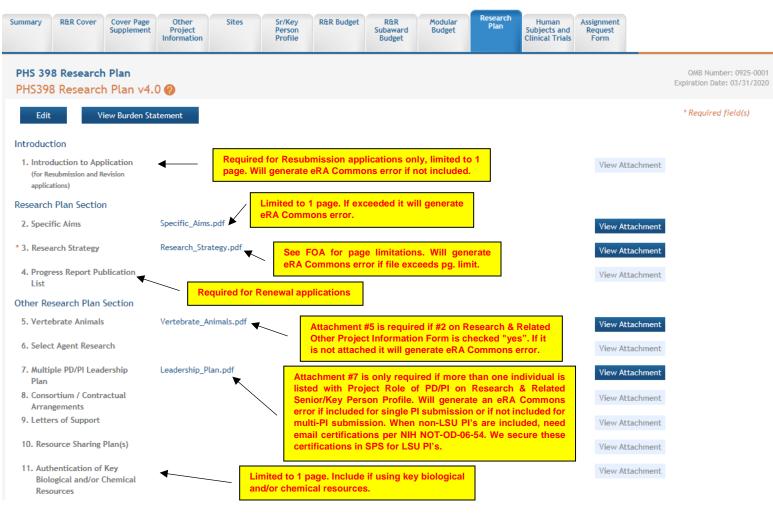
		Months					
Project Role	Cal	Acad.	Sum.	Requested Salary (\$)	Frin	nge Benefits (\$)	Funds Requested (\$)
1 Post Doctoral Associates	12.00	0.00	0.00	35,000.00		15,400.00	50,400
2 Graduate Students	12.00	0.00	0.00	40,000.00		0.00	40,000
Undergraduate Students							
Secretarial/Clerical							
Total Number Other Personnel							
	Total O	ther Personnel			\$	90,400.00	
	Total Sa	alary, Wages and	d Fringe Benefit	s (A+B)	\$	124,960.00	
tion							
	ent Item					Funds Requested	l (S)
ent					١	View Attachment	
ent	Total fu	unds requested	for all equipmer	it listed in the attached file	S	View Attachment	
ent		unds requested t	for all equipmer	it listed in the attached file		View Attachment	
ent			for all equipmer	it listed in the attached file	s		
ent			for all equipmer	it listed in the attached file	s s		
ent	Total E	quipment estic Travel Cos		nt listed in the attached file	s s	0.00	
ent	Total E	quipment	ts (Incl. Canada,		S S Fund	0.00 Is Requested (\$)	
	 Post Doctoral Associates Graduate Students Undergraduate Students Secretarial/Clerical Total Number Other Personnel 	1 Post Doctoral Associates 12.00 2 Graduate Students 12.00 Undergraduate Students Secretarial/Clerical Total Number Other Personnel Total O Total Secretarial Secretaria	Project Role Cal Acad. 1 Post Doctoral Associates 12.00 0.00 2 Graduate Students 12.00 0.00 Undergraduate Students Secretarial/Clerical Total Number Other Personnel Total Salary, Wages and Salary, Wag	Project Role Cal Acad. Sum. 1 Post Doctoral Associates 12.00 0.00 0.00 2 Graduate Students 12.00 0.00 0.00 Undergraduate Students Secretarial/Clerical Total Number Other Personnel Total Salary, Wages and Fringe Benefit Action Secretarial/Clerical Total Salary, Wages and Fringe Benefit Total Salary, Wages and Fringe Benefit	Project Role Cat Acad. Sum. Requested Salary (\$) 1 Post Doctoral Associates 12.00 0.00 0.00 35,000.00 2 Graduate Students 12.00 0.00 0.00 40,000.00 Undergraduate Students Secretarial/Clerical Total Number Other Personnel Total Salary, Wages and Fringe Benefits (A+B) vettor Equipment Item Equipment Item Vettor Vettor	Project Role Cal Acad. Sum. Requested Salary (\$) Frint 1 Post Doctoral Associates 12.00 0.00 0.00 35,000.00 40,000.00 2 Graduate Students 12.00 0.00 0.00 40,000.00 40,000.00 1 Undergraduate Students Secretarial/Clerical Total Number Other Personnel Total Salary, Wages and Fringe Benefits (A+B) \$ Setter Equipment Item	Project Role Cal Acad. Sum. Requested Salary (\$) Fringe Benefits (\$) 1 Post Doctoral Associates 12.00 0.00 0.00 35,000.00 15,400.00 2 Graduate Students 12.00 0.00 0.00 40,000.00 0.00 Undergraduate Students Sceretarial/Clerical Total Number Other Personnel Total Jerry. Wages and Fringe Benefits (A+B) \$ 90,400.00 Destruct Equipment Item Equipment Item 5 124,960.00

Total Senior/Key Person

*Continued on next page

		Funds	Requested (\$)	
	1. Tuition/Fees/Health Insurance	s		
Unless specifically stated in the FOA, NIH applicants should leave blank.	2. Stipends	S		
	3. Travel	S		
	4. Subsistence	s		
	5. Other	s		
	Number of Participants/Trainees			
	Total Participant/Trainee Support Costs	s	0.00	
	5. 5%			
Other Direct Costs				
		Funds	Requested (\$)	
	1. Materials and Supplies	S	27,664.00	
	2. Publication Costs	s	3,000.00	
	3. Consultant Services	s		
	4. ADP/Computer Services	s		
	5. Subawards/Consortium/ Contractual Costs	s	32,503.00	
	6. Equipment or Facility Rental/User Fees	s		
	7. Alterations and Renovations	s		
	8. Other: Histology, Mice Housing, & Service Contracts	s	54,000.00	
	9.	s		
If Direct Costs less Consortium F&A are <\$250k each	9.	2		
year, then you should use the NIH Modular Budget and not this budget.	10.	S		
	Total Other Direct Costs	S	117,167.00	
Direct Costs If Direct Costs less Consortium F&A are equal				
to or > \$500,000 in any year of the project, Pl	Total Direct Costs (A thru F)	s	244,127.00	
must include prior approval from NIH in the Cover Letter attachment. NOT-OD-17-005	Total Direct Costs (A tillu P)	2	244,127.00	
Indirect Costs				
Indirect Cost Type	Indirect Cost Rate (%) Indirect Cost	t Base (\$)	Funds Reque	sted (S)
fied Total Direct Costs - MTDC	48.00	332,373.0	0	159,539.0
Total Direct Cost less equipment, tuition remission, participation support costs, and subawards in				
excess of \$25,000 each.	Total Indirect Costs	S	159,539.00	
Ognizant Federal Agency DHHS, Arif Karim, 214-767-3261				
Agency Name, POC Name and POC 'hone Number)				
49.459-1450-1400-9764-11 				
otal Direct and Indirect Costs				
Check FOA for any program specific	Total Direct and Indirect Institutional Costs (G + H)	S	403,666.00	
Tèe				
	Funds Requested	s		
	i unus nequesteu	2		
Total Costs and Fee				
Total Costs and Fee				
Total Costs and Fee	Funds Requested	s	403,666.00	
Total Costs and Fee Budget Justification	Funds Requested	5	403,666.00	





Appendix

12. Appendix

 Attachment File Name
 View Attachment

 Nothing found to display.
 All attachments must be in PDF. Use one space (not two or more) between words or characters. Avoid use of ampersand (&) in the name. File name should be 50 characters or less.
 View Attachment

Summary	R&R Cover	Cover Page Supplement	Other Project Information	Sites	Sr/Key Person Profile	R&R Budget	R&R Subaward Budget	Modular Budget	Research Plan	Human Subjects and Clinical Trials	Assignment Request Form	
	-		inical Trials Clinical Tr			.0 🕜						OMB Number: 0925-0001 and 0925-0002 Expiration Date: 03/31/2020
Edit		w Burden State	ement									* Required field(s)
			<mark>k "Edit" in o</mark>	r <mark>der to add i</mark>	nformation	to section						
Plea	se complete	the human su	bjects section	of the Resea	arch & Relate	d Other Projec	t Informatio	n form prior	to completing	this form.		
	ds must be ma					ject Informatio tion form and I			-		hanges to these lete on this	
Ar	e Human Sub	jects Involve	ed?			• Yes ON	0					
Is	the Project E	Exempt from	Federal regul	ations?		O Yes No	0					
Ex	emption num	nber:				1 2	3 4	5 6	7 8			
Other F Informa Study Attach	Requested ation Record(s)	ct study recor	ds using uniqu	ie filenames.	load Study	Add Attach		lete Attachm		tachment		
	ry #			Study Title			Clinic	al Trial?		Action		
Delaye	g found to di: ed Onset Stu New Delayed	udy(ies)	The f	ollowing p		ord" informat what popula udy".						
Entry	/ # g found to di		udy Title		Anticipa Clinical T		Justi	fication		Add/Upda	ate View ent Attachmen	it.
	5 .eand to u	-1.22	Save a	nd Keep Lock	save a	nd Release Loc	c <mark>k</mark> Cance	el and Releas	e Lock			

PHS Human Subjects and Clinical Trials PHS Human Subjects and Clinical Tri	OMB Number: 0925-0001 and 0925-0007 Expiration Date: 03/31/2020			
Edit			Expand All	* Required field(s)
SECTION 1 - BASIC INFORMATION				•
* 1.1. Study Title (each study title must be unique)				
* 1.2. Is this Study Exempt from Federal Regulations?	○ Yes ○ No			
1.3. Exemption Number	1 2 3 4 5	6 7 8		
* 1.4. Clinical Trial Questionnaire				
If the answers to all four questions below are ye	s, this study meets the definition	of a Clinical Trial.		
1.4.a. Does the study involve human participa	nts?	🔿 Yes 🔿 No		
1.4.b. Are the participants prospectively assig intervention?	ned to an	○ Yes ○ No		
1.4.c. Is the study designed to evaluate the ef intervention on the participants?	fect of the	○ Yes ○ No		
1.4.d. Is the effect that will be evaluated a he biomedical or behavioral outcome?	alth-related	○ Yes ○ No		
1.5. Provide the ClinicalTrials.gov Identifier (e.g.,	NCT87654321) for this trial, if a	applicable		
Click the Populate button to retrieve data from	ClinicalTrials.gov registration one	e Identifier is entered.		
Populat	e			

		2.1. Conditions or	Focus of Study			Action
othing found to display						
Add New Condition						
2. Eligibility Criteria						
Enter up to 15000 cha	uracters					
3. Age Limits	Minimum Age	~	Maximum Age	V	Characters Ren	naining: 15000
 Inclusion of Women, Minorities, and Children 			Add Attachment	Delete Attachment	View Attachment	
5. Recruitment and Retention Plan)		Add Attachment	Delete Attachment	View Attachment	
6. Recruitment Status		~				
7. Study Timeline			Add Attachment	Delete Attachment	View Attachment	
8. Enrollment of First Subject		•	·			
clusion Enrollment Re						
Add New Inclusion En	rollment Report					
	ent Location Type		Location		Action	

Inclusion Enrollment Report 1 PHS Human Subjects and Clinical Trials Information v1.0 @

Edit

* 1. Using an Existing Dataset or Resource	○ Yes ○ No	
* 2. Enrollment Location Type	O Domestic O Foreign	
3. Enrollment Country(ies)	None selected 👻	
4. Enrollment Location(s)	Enter up to 255 characters	
		Characters Remaining: 255
5. Comments	Enter up to 500 characters	

Characters Remaining: 500

Planned

	Ethnic Categories									
	Not Hispani	c or Latino	Hispanic	Total						
Racial Categories	Female	Male	Female	Male						
American Indian/Alaska Native	0	0	0	0	0					
Asian	0	0	0	0	0					
Native Hawaiian or Other Pacific Islander	0	0	0	0	0					
Black or African American	0	0	0	0	0					
White	0	0	0	0	0					
More than One Race	0	0	0	0	0					
Total	0	0	0	0	0					

Cumulative (Actual)

					Ethnic C	ategories				
	Not H	lispanic or La	atino	His	panic or Lati	no	Unknown/	Not Reported	l Ethnicity	Total
Racial Categories	Female	Male	Unknown/N ot Reported	Female	Male	Unknown/N ot Reported	Female	Male	Unknown/N ot Reported	
American Indian/Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0
CTION 3 - PROTECTIO	TINOM DNA NO	Foring plan	15					_	the "Study Reco	ord" informatic
3.1. Protection of					Add Attack	pront Dela	te Attachmen	t View Atta	chmont	
Human Subject	ts									
3.2. Is this a multi-s O Yes O No (If yes, describe		t will use th	e same protoc	ol to conduct						c site?
single IRB plan					Add Attach		te Attachmen			
3.3. Data and Safety Monitoring Plar					Add Attack	nment Dele	te Attachmen	t View Atta	achment	
3.4. Will a Data and this study?	Safety Monit	oring Board	be appointed	for ()	Yes 🔿 No					
3.5. Overall Structu the Study Tean					Add Attack	hment Dele	te Attachmen	t View Atta	achment	
CTION 4 - PROTOCOL	SYNOPSIS									
4.1. Brief Summary		Entor up t	to 5000 Charact	-						
		Enter up t		.ers						
4.2 Shudu Danim								Characte	ers Remaining: 5	000
4.2. Study Design										
4.2.a. Narrative Description		Enter up t	to 32000 Charad	cters						
								Character	s Remaining: 32	000
4.2.b. Primary F	ourpose	1		~						

4.2.c. Interventions

Intervention	n Type	Name	Description	Action
	~	Enter up to 200 Characters	Enter up to 1000 Characters	Delete
Add New Inte	erventio	1		
4.2.d. Study F	hase		\checkmark	
		Is this an NIH-defined Phas	se III clinical trial? O Yes O No	
4.2.e. Interve Model	ention	\checkmark		
4.2.f. Masking	3	○ Yes ○ No		
		Participant Care P	rovider 🗌 Investigator 🗌 Outcomes Assessor	
4.2.g. Allocat	ion	\checkmark		

4.3. Outcome Measures

Туре	Name	Time Frame		Brief Descri	ption	Action
~	Enter up to 255 Characters	Enter up to 255 Characters	Enter up to 999	Ocharacters		Delete
Add New Outco	ome					
4.4. Statistical and Power	· · · · · · · · · · · · · · · · · · ·	Α	dd Attachment	Delete Attachment	View Attachment	
4.5. Subject Participatio Duration	on					
4.6. Will the stu interventio	udy use an FDA-regulated on?	○ Yes ○ No				
4.6.a. If yes statu		f Investigational Product (IP) an	d Investigational	l New Drug (IND)/Inve	stigational Device E	xemption (IDE)
		A	dd Attachment	Delete Attachment	View Attachment	
4.7. Disseminat	ion Plan	A	dd Attachment	Delete Attachment	View Attachment	
	Save and Keep Lock	Save and Release Lock Save	and Add Ca	ancel and Release Loci	c Remove Study	
		×	Click "	'Save and Add" once y	ou have completed t	his section.

PHS Human Subjects and Clinical Trials Information PHS Human Subjects and Clinical Trials Information v1.0 @

Edit View Burde	en Statement			* Required fie	eld(s)	
Please complete the hum	an subjects section of the Research	& Related Other Project Inform	nation form prior to co	mpleting this form.		
	aken from the Research & Related C ne Research & Related Other Project		1 A A			
Are Human Subjects Inv	volved?	● Yes ○ No				
Is the Project Exempt from Federal regulations?		○ Yes				
Exemption number: 1 2 3 4 5 6 7 8				7 🗌 8		
If Yes to Human Subjects						
In some cases a study ca	oposed Human Subject Study by sele nnot have defined plans for human s Study' to provide the study name ar	subject involvement per agenc			t	
Other Requested Information		Add Attachment	Delete Attachment	View Attachment		
Study Record(s)						

Attach human subject study records using unique filenames.

Add New S	itudy Download Study	Upload Study		
		itudy Title	Clin	ical Trial?
: 1			No	

Delayed Onset Study(ies)

Add New	v Delayed Onset Study	Click to add a Delayed Onset Study	<mark>/(ies).</mark>			
Entry #	Study Title	Anticipated Clinical Trial?	Justification	Delete on Save	Add/Update Attachment	
Nothing fou	und to display.					
				_		

Save and Keep Lock Save and Release Lock Cancel and Release Lock

Add New Delay	red Onset Study					
Entry #	Study Title	Anticipated Clinical Trial?	Justification	Delete on Save	Add/Update	
1 *		* () Yes () No *			Add	
	Save and Keep Loo	ck Save and Rele	ease Lock Cancel and Release Loc	:k		

Delayed Onset Study(ies)