### 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 03:42:29.000 PM EST  

### FOA Information:

**FOA Information:** PA-18-603  
**Opportunity Title:** Women and Sex/Gender Differences in Drug and Alcohol Abuse/Dependence (RO1 Clinical Trial Optional)  
**Agency:** National Institutes of Health  
**CFDA Number:** FORMS-E  
**Competition ID:**  
**Competition Title:** Use for due dates on or after January 25, 2018  
**Opportunity Open Date:** 05/05/2018  
**Opportunity Close Date:** 05/07/2021  
**Agency Contact:**  

**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]

---

**Closing date should be after submission or will generate Grants.gov error.**
Required for Resubmission and Renewal. This is your NIH proposal number. Example: For proposal 1R01CA123456-01 enter CA123456. If not entered it will generate an eRA Commons error.
Generates an eRA Commons error if not entered.

Unique to NIH. Generates an eRA Commons error if not entered correctly.

Check Resubmissions or Renewal as appropriate

Make sure dates match the budget pages.
13. **CONGRESSIONAL DISTRICT OF APPLICANT**

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

14. **PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION**

<table>
<thead>
<tr>
<th>Prefix</th>
<th>Dr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>* First Name</td>
<td>PI First Name</td>
</tr>
<tr>
<td>* Middle Name</td>
<td>PI Middle Name</td>
</tr>
<tr>
<td>* Last Name</td>
<td>PI Last Name</td>
</tr>
<tr>
<td>* Suffix</td>
<td>PI Suffix</td>
</tr>
<tr>
<td>* Position/Title</td>
<td>PI Title</td>
</tr>
<tr>
<td>* Organization Name</td>
<td>LOUISIANA STATE UNIVERSITY ABM COLLEGE</td>
</tr>
<tr>
<td>Department</td>
<td>PI Department</td>
</tr>
<tr>
<td>Division</td>
<td>PI Division</td>
</tr>
<tr>
<td>* Street 1</td>
<td>PI Street 1</td>
</tr>
<tr>
<td>Street 2</td>
<td>PI Street 2</td>
</tr>
<tr>
<td>* City</td>
<td>BATON ROUGE</td>
</tr>
<tr>
<td>County/Parish</td>
<td>PI County/Parish</td>
</tr>
<tr>
<td>* State</td>
<td>Louisiana</td>
</tr>
<tr>
<td>Province</td>
<td>PI Province</td>
</tr>
<tr>
<td>* Country</td>
<td>UNITED STATES</td>
</tr>
<tr>
<td>Zip/Postal Code</td>
<td>708030001</td>
</tr>
<tr>
<td>* Phone Number</td>
<td>PI Phone Number</td>
</tr>
<tr>
<td>Fax Number</td>
<td>PI Fax Number</td>
</tr>
<tr>
<td>* Email</td>
<td><a href="mailto:PI_email@lsu.edu">PI_email@lsu.edu</a></td>
</tr>
</tbody>
</table>

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 |
| d. Estimated Program Income | 0.00 |

*Continued on next page*
See FOA requirements. If not applicable, answer "Program is Not Covered..." If applicable, answer "Program has not been selected..."

Required for some FOAs. Use optional Assignment Request Form to request assignment to a particular institute and/or Study Section, provide reviewer conflicts or interest, etc.
1. Vertebrate Animals Section
   Are vertebrate animals euthanized?  
   □ Yes  □ No
   If "Yes" to euthanasia, method consistent with American Veterinary Medical Association (AVMA) guidelines?  
   □ Yes  □ No
   If "No" to AVMA guidelines, describe method and provide scientific justification.

2. Program Income Section
   Is 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.

<table>
<thead>
<tr>
<th>Budget Period</th>
<th>Anticipated Amount ($)</th>
<th>Source(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. Human Embryonic Stem Cells Section
   Does the proposed project involve human embryonic stem cells?  
   □ Yes  □ 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: [link]. 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
     If "Yes" then answer the following:
     □ Previously Reported

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

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.

Must answer if animal research is involved. Will generate an eRA commons error if not done.
**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.

**Application Information**

- If exemption is "yes" must check exemption # box
- If answer is "No" then you must enter IRB approval date and Human Subjects Assurance #. If "Yes" then you must enter Human Subject Assurance #. If not complete will generate eRA Commons error.
- Will generate eRA Commons error if #2 is checked "Yes" and this is blank
- If "Yes", refer to instructions on how to label proprietary information

**Limited to 30 lines of text. If exceeded it will generate an eRA commons error.**

**Limited to 2-3 sentences. If exceeded it will generate an eRA commons error.**

All attachments must be in PDF. Use one space (not two or more) between words or characters. Avoid use of ampersand (&) in file name. File name should be 50 characters or less.
All editable fields marked with * must be entered in order to Save this form. Please gather these data before beginning your data entry.

- I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization. Do not check, it will generate eRA Commons error

- Generates eRA Commons error if not entered
Do not check, it will generate eRA Commons error

Enter Subrecipient's DUNS #

Enter Subrecipient's congressional district

Example of what you see after you have entered all the information above and saved it.
PI eRA Commons username is required.

* Required field(s)

Click this after entering username to populate fields.

PI eRA Commons username is required.

*Continued on next page
If the degree does not match the PI's eRA Commons personal profile, this may generate eRA Commons warning.
If additional Senior/Key Personnel:

**Or Other Significant Contributors**

PROFILE - Senior/Key Person 1

- **Credential, e.g., agency login**
- **Prefix**
- **First Name**
- **Middle Name**
- **Last Name**
- **Suffix**
- **Position/Title**
- **Department**
- **Organization Name**
  - LOUISIANA STATE UNIVERSITY A&M COLLEGE
- **Division**
- **Street 1**
- **Street 2**
- **City**
- **County/Parish**
- **State**
  - Louisiana
- **Province**
- **Country**
- **Zip/Postal Code**
  - 708030001
- **Phone Number**
- **Fax Number**
- **E-Mail**
  - co__@lsu.edu
- **Project Role**
  - Co-Investigator

- **Other Project Role Category**
- **Degree Type**
- **Degree Year**

- **Attach Biographical Sketch**
  - Bio_Sketch.pdf
  - **Replace Attachment**
  - **Delete Attachment**
  - **View Attachment**

- **Attach Current & Pending Support**

**Organization name for all senior personnel is required**

**Bio Sketch is limited to 5 pages. If exceeded it will generate an eRA Commons error.**

The role of "Co-PI/Co-PD" is not appropriate for multi-PI submissions. Will generate eRA Commons warning. For multi-PI submission, use role of "PD/PI" and include eRA Commons username in Credential field. Also include Multiple PI Leadership Plan on PHS 398 Research Plan Form. When non-LSU PI's are included, need email certifications from the non-LSU PI as required under NIH NOT-OD-06-054. We secure these certifications in SPS for LSU PI's.

**Other Significant Contributors (OSC) should be listed with Project Role: Other (Specify) and Other Project Role Category: Other Significant Contributor OSC should be listed last after all Senior/Key Personnel.**
This should only be completed for Senior/Key Personnel and Other Significant Contributors. eRA Commons usernames can be included for everyone, but are only required for individuals with a role of PD/PI.

Effort greater than zero is required for ALL senior personnel per NIH guidelines. Fiscal year employee effort should be under Cal. Months. Academic year employee effort should be under Acad. and/or Sum Months. Generates eRA Commons error if effort is zero.
B. Other Personnel

<table>
<thead>
<tr>
<th>Number of Personnel</th>
<th>Project Role</th>
<th>Months</th>
<th>Requested Salary ($)</th>
<th>Fringe Benefits ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Cal</td>
<td>Acad.</td>
<td>Sum.</td>
<td>35,000.00</td>
</tr>
<tr>
<td>1</td>
<td>Post Doctoral Associates</td>
<td>12.00</td>
<td>0.00</td>
<td>0.00</td>
<td>35,000.00</td>
</tr>
<tr>
<td>2</td>
<td>Graduate Students</td>
<td>12.00</td>
<td>0.00</td>
<td>0.00</td>
<td>40,000.00</td>
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<tr>
<td></td>
<td>Undergraduate Students</td>
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<tr>
<td></td>
<td>Secretarial/Clerical</td>
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<td></td>
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<tr>
<td>3</td>
<td>Total Number Other Personnel</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Total Other Personnel $90,400.00
Total Salary, Wages and Fringe Benefits (A+B) $124,940.00

C. Equipment Description

<table>
<thead>
<tr>
<th>Equipment Item</th>
<th>Funds Requested ($)</th>
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<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

Nothing found to display.

D. Travel

<table>
<thead>
<tr>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

1. Domestic Travel Costs (incl. Canada, Mexico, and U.S. Possessions) $2,000.00
2. Foreign Travel Costs $0.00
Total Travel Costs $2,000.00

*Continued on next page*
Unless specifically stated in the FOA, NIH applicants should leave blank.

Check FOA for any program specific restrictions on total requested funds.

If Direct Costs less Consortium F&A are equal to or > $500,000 in any year of the project, PI must include prior approval from NIH in the Cover Letter attachment. NOT-OD-17-005

If Direct Costs less Consortium F&A are <$250k each year, then you should use the NIH Modular Budget and not this budget.

Total Direct Cost less equipment, tuition remission, participation support costs, and subawards in excess of $25,000 each.

Check FOA for any program specific restrictions on total requested funds.
Required for proposals that include subrecipients when the R&R Budget is used. Download subaward form and send to Subrecipient to complete & return. Then attach subaward form.

To add click on Optional Forms in Left Menu

To be used when Direct Cost less Consortium F&A are <$250k in each year.

Make sure dates match SF 424 (R&R)

If Direct Cost less consortium F&A is >$250k in any year of the project, then the R&R Budget should be used.

Required for budgets with Subrecipients

Only needed if the number of modules requested for each year varies.
Required for Resubmission applications only, limited to 1 page. Will generate eRA Commons error if not included.

Limited to 1 page. If exceeded it will generate eRA Commons error.

See FOA for page limitations. Will generate eRA Commons error if file exceeds pg. limit.

Required for Renewal applications

Attachment #5 is required if #2 on Research & Related Other Project Information Form is checked "yes". If it is not attached it will generate eRA Commons error.

Attachment #7 is only required if more than one individual is listed with Project Role of PD/PI on Research & Related Senior/Key Person Profile. Will generate an eRA Commons error if included for single PI submission or if not included for multi-PI submission. When non-LSU PI's are included, need email certifications per NIH NOT-OD-06-54. We secure these certifications in SPS for LSU PI's.

Limited to 1 page. Include if using key biological and/or chemical resources.

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.
Click "Edit" in order to add information to section.

The following pages show what populates when you click "Add New Study".

**Study Record(s)**

Attach human subject study records using unique filenames.

<table>
<thead>
<tr>
<th>Entry #</th>
<th>Study Title</th>
<th>Clinical Trial?</th>
<th>Anticipated Clinical Trial?</th>
<th>Justification</th>
<th>Delete on Save</th>
<th>Add/Update Attachment</th>
<th>View Attachment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Nothing found to display.
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
   - Does the study involve human participants?  
     - Yes  
     - No
   - Are the participants prospectively assigned to an intervention?  
     - Yes  
     - No
   - Is the study designed to evaluate the effect of the intervention on the participants?  
     - Yes  
     - No
   - Is the effect that will be evaluated a health-related biomedical or behavioral outcome?  
     - Yes  
     - No

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable
   Click the Populate button to retrieve data from ClinicalTrials.gov registration once identifier is entered.
### 2.1. Conditions or Focus of Study

<table>
<thead>
<tr>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nothing found to display</td>
</tr>
</tbody>
</table>

#### Add New Condition

**2.2. Eligibility Criteria**

Enter up to 15000 characters

Characters Remaining: 15000

#### 2.3. Age Limits

<table>
<thead>
<tr>
<th>Minimum Age</th>
<th>Maximum Age</th>
</tr>
</thead>
</table>

#### 2.4. Inclusion of Women, Minorities, and Children

Add Attachment | Delete Attachment | View Attachment

#### 2.5. Recruitment and Retention Plan

Add Attachment | Delete Attachment | View Attachment

#### 2.6. Recruitment Status

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
</table>

#### 2.7. Study Timeline

Add Attachment | Delete Attachment | View Attachment

#### 2.8. Enrollment of First Subject

Add Attachment

### Inclusion Enrollment Report(s)

<table>
<thead>
<tr>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Add New Inclusion Enrollment Report</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Entry #</th>
<th>Enrollment Location Type</th>
<th>Enrollment Location</th>
<th>Action</th>
</tr>
</thead>
</table>

Nothing found to display.
# 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**
   - Domestic
   - Foreign

3. **Enrollment Country(ies)**
   - None selected

4. **Enrollment Location(s)**
   - Enter up to 255 characters

5. **Comments**
   - Enter up to 500 characters

---

## Planned

<table>
<thead>
<tr>
<th>Racial Categories</th>
<th>Ethnic Categories</th>
<th>Not Hispanic or Latino</th>
<th>Hispanic or Latino</th>
<th>Total</th>
</tr>
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<tbody>
<tr>
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<td></td>
<td>Female</td>
<td>Male</td>
<td>Female</td>
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<tr>
<td>American Indian/Alaska Native</td>
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<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asian</td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
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<td>Black or African American</td>
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<tr>
<td>More than One Race</td>
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<td>Total</td>
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</table>
Click “Save and Add” once you have completed this section. Once then saved and added you can finish the “Study Record” information.
**4.2.c. Interventions**

<table>
<thead>
<tr>
<th>Intervention Type</th>
<th>Name</th>
<th>Description</th>
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<tbody>
<tr>
<td></td>
<td>Enter up to 200 Characters</td>
<td>Enter up to 1000 Characters</td>
</tr>
</tbody>
</table>

**Add New Intervention**

**4.2.d. Study Phase**

- Is this an NIH-defined Phase III clinical trial? [ ] Yes [ ] No

**4.2.e. Intervention Model**

**4.2.f. Masking**

- [ ] Yes [ ] No
- [ ] Participant [ ] Care Provider [ ] Investigator [ ] Outcomes Assessor

**4.2.g. Allocation**

**4.3. Outcome Measures**

<table>
<thead>
<tr>
<th>Type</th>
<th>Name</th>
<th>Time Frame</th>
<th>Brief Description</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Enter up to 255 Characters</td>
<td>Enter up to 255 Characters</td>
<td>Enter up to 999 Characters</td>
</tr>
</tbody>
</table>

**Add New Outcome**

**4.4. Statistical Design and Power**

**4.5. Subject Participation Duration**

**4.6. Will the study use an FDA-regulated intervention?**

- [ ] Yes [ ] No

**4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status**

**4.7. Dissemination Plan**

- [ ] Add Attachment [ ] Delete Attachment [ ] View Attachment

**Additional Buttons:**

- Save and Keep Lock
- Save and Release Lock
- Save and Add
- Cancel and Release Lock
- Remove Study

---

Click “Save and Add” once you have completed this section.
Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.

The following items are taken from the Research & Related Other Project Information form and displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project Information form and may impact the data items you are required to complete on this form.

Are Human Subjects Involved?  ☐ Yes  ☐ No
Is the Project Exempt from Federal regulations?  ☐ Yes  ☐ No
Exemption number:  □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8

If Yes to Human Subjects
Add a record for each proposed Human Subject Study by selecting 'Add New Study'.
In some cases a study cannot have defined plans for human subject involvement per agency policies on Delayed Onset Studies. In these cases, select 'Add New Delayed Onset Study' to provide the study name and justification for omission of human subjects study information.

Study Record(s)
Attach human subject study records using unique filenames.

Delayed Onset Study(ies)

Nothing found to display.
### Delayed Onset Study(ies)

<table>
<thead>
<tr>
<th>Entry #</th>
<th>Study Title</th>
<th>Anticipated Clinical Trial?</th>
<th>Justification</th>
<th>Delete on Save</th>
<th>Add/Update Attachment</th>
<th>View Attachment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>○ Yes ○ No</td>
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<td></td>
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</tbody>
</table>

**Buttons:**
- Save and Keep Lock
- Save and Release Lock
- Cancel and Release Lock